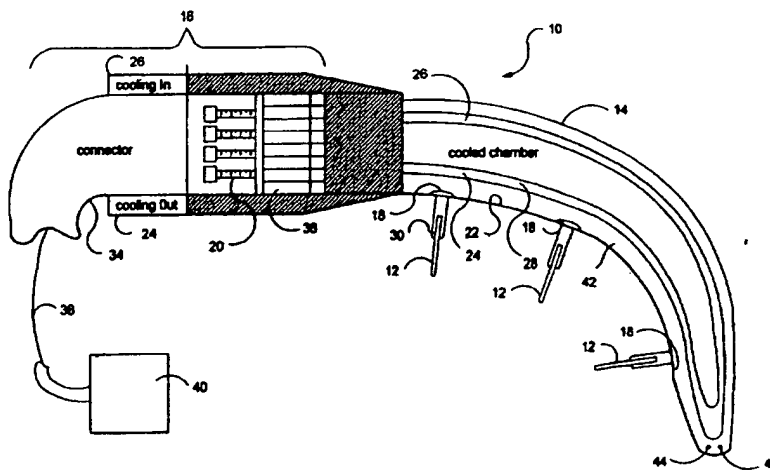




INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶ : A61B 17/39		A1	(11) International Publication Number: WO 97/43972
			(43) International Publication Date: 27 November 1997 (27.11.97)
(21) International Application Number: PCT/US97/08830		(74) Agent: DAVIS, Paul; Wilson Sonsini Goodrich & Rosati, 650 Page Mill Road, Palo Alto, CA 94304-1050 (US).	
(22) International Filing Date: 22 May 1997 (22.05.97)			
(30) Priority Data:		(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, HU, IL, IS, JP, KE, KG, KP, KR, KZ, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ARIPO patent (GH, KE, LS, MW, SD, SZ, UG), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).	
08/651,800 22 May 1996 (22.05.96) US			
08/695,802 12 August 1996 (12.08.96) US			
(60) Parent Applications or Grants			
(63) Related by Continuation			
US 08/695,802 (CIP)			
Filed on 12 August 1996 (12.08.96)			
US 08/651,800 (CIP)			
Filed on 22 May 1996 (22.05.96)			
(71) Applicant (for all designated States except US): SOMNUS MEDICAL TECHNOLOGIES, INC. [US/US]; 285 N. Wolfe Road, Sunnyvale, CA 94086 (US).		Published With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.	
(72) Inventor; and			
(75) Inventor/Applicant (for US only): EDWARDS, Stuart, D. [US/US]; 658 Westridge Drive, Portola Valley, CA 94028 (US).			

(54) Title: METHOD AND APPARATUS FOR TREATMENT OF AIR WAY OBSTRUCTIONS



(57) Abstract

An apparatus that reduces a volume of a selected site in an interior of the tongue includes a handpiece and an electrode at least partially positioned in the interior of the handpiece. The electrode includes an electrode electromagnetic energy delivery surface which is advanceable from the interior of the handpiece into the interior of the tongue. An electrode advancement member is coupled to the electrode and configured to advance the electrode an advancement distance in the interior of the tongue. The advancement distance is sufficient for the electrode electromagnetic energy delivery surface to deliver electromagnetic energy to the selected tissue site and reduce a volume of the selected site without damaging a hypoglossal nerve. A cable is coupled to the electrode.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece	ML	Mali	TR	Turkey
BG	Bulgaria	HU	Hungary	MN	Mongolia	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MR	Mauritania	UA	Ukraine
BR	Brazil	IL	Israel	MW	Malawi	UG	Uganda
BY	Belarus	IS	Iceland	MX	Mexico	US	United States of America
CA	Canada	IT	Italy	NK	Niger	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NL	Netherlands	VN	Viet Nam
CG	Congo	KE	Kenya	NO	Norway	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NZ	New Zealand	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	PL	Poland		
CM	Cameroon	KR	Republic of Korea	PT	Portugal		
CN	China	KZ	Kazakstan	RO	Romania		
CU	Cuba	LC	Saint Lucia	RU	Russian Federation		
CZ	Czech Republic	LI	Liechtenstein	SD	Sudan		
DE	Germany	LK	Sri Lanka	SE	Sweden		
DK	Denmark	LR	Liberia	SG	Singapore		
EE	Estonia						

METHOD AND APPARATUS FOR TREATMENT OF AIR WAY OBSTRUCTIONS

Cross-Reference to Related Applications

5 This application is a continuation-in-part application of U.S. Patent
Application No. 08/651,800, entitled "METHOD AND APPARATUS FOR
TREATMENT OF AIR WAY OBSTRUCTIONS", filed May 22, 1996, which is
a continuation-in-part application of U.S. Patent Application No. 08/642,053,
entitled "METHOD FOR TREATMENT OF AIRWAY OBSTRUCTIONS",
10 filed May 3, 1996, which is a continuation-in-part application of U.S. Patent
Application No. 08/606,195, filed February 23, 1996, entitled "Method for
Treatment of Airway Obstructions", which cross-references U.S. Patent
Application No. 08/516,781 filed August 18, 1995, entitled "Ablation Apparatus
and System for Removal of Soft Palate Tissue", having named inventors Stuart
D. Edwards, Edward J. Gough and David L. Douglass, which is a continuation-
15 in-part of U.S. Application No. 08/239,658, filed May 9, 1994 entitled "Method
for Reducing Snoring by RF Ablation of the Uvula", all incorporated by
reference herein.

BACKGROUND OF THE INVENTION

Field of the Invention

20 This invention relates to an apparatus for the treatment of air way
obstructions, and more particularly to an apparatus for reducing a volume of a
selected site of an interior of the tongue, and more particularly to an apparatus
for ablating a selected site of an interior of the tongue without damaging a
hypoglossal nerve.

Description of Related Art

25 Sleep-apnea syndrome is a medical condition characterized by daytime
hypersomnolence, morning arm aches, intellectual deterioration, cardiac
arrhythmias, snoring and thrashing during sleep. It is caused by frequent
episodes of apnea during the patient's sleep. The syndrome is classically
30 subdivided into two types. One type, termed "central sleep apnea syndrome", is

characterized by repeated loss of respiratory effort. The second type, termed obstructive sleep apnea syndrome, is characterized by repeated apneic episodes during sleep resulting from obstruction of the patient's upper airway or that portion of the patient's respiratory tract which is cephalad to, and does not
5 include, the larynx.

Treatment thus far includes various medical, surgical and physical measures. Medical measures include the use of medications such as protriptyline, medroxyprogesterone, acetazolamide, theophylline, nicotine and other medications in addition to avoidance of central nervous system depressants
10 such as sedatives or alcohol. The medical measures above are sometimes helpful but are rarely completely effective. Further, the medications frequently have undesirable side effects.

Surgical interventions have included uvulopalatopharyngoplasty, tonsillectomy, surgery to correct severe retrognathia and tracheostomy. In one
15 procedure the jaw is dislodged and pulled forward, in order to gain access to the base of the tongue. These procedures may be effective but the risk of surgery in these patients can be prohibitive and the procedures are often unacceptable to the patients.

Physical measures have included weight loss, nasopharyngeal airways, nasal CPAP and various tongue retaining devices used nocturnally. These
20 measures may be partially effective but are cumbersome, uncomfortable and patients often will not continue to use these for prolonged periods of time. Weight loss may be effective but is rarely achieved by these patients.

In patients with central sleep apnea syndrome, phrenic nerve or
25 diaphragmatic pacing has been used. Phrenic nerve or diaphragmatic pacing includes the use of electrical stimulation to regulate and control the patient's diaphragm which is innervated bilaterally by the phrenic nerves to assist or support ventilation. This pacing is disclosed in *Direct Diaphragm Stimulation* by J. Mugica et al. PACE vol. 10 Jan-Feb. 1987, Part II, *Preliminary Test of a Muscular Diaphragm Pacing System on Human Patients* by J. Mugica et al.
30 from *Neurostimulation: An Overview* 1985 pp. 263-279 and *Electrical*

Activation of Respiration by Nochomovitez IEEE Eng. in Medicine and Biology, June, 1993.

However, it was found that many of these patients also have some degree of obstructive sleep apnea which worsens when the inspiratory force is augmented by the pacer. The ventilation induced by the activation of the diaphragm also collapses the upper airway upon inspiration and draws the patient's tongue inferiorly down the throat choking the patient. These patients then require tracheostomies for adequate treatment.

A physiological laryngeal pacemaker as described in *Physiological Laryngeal Pacemaker* by F. Kaneko et al. from Trans Am Soc Artif Intern Organs 1985 senses volume displaced by the lungs and stimulates the appropriate nerve to open the patient's glottis to treat dyspnea. This apparatus is not effective for treatment of sleep apnea. The apparatus produces a signal proportional in the displaced air volume of the lungs and thereby the signal produced is too late to be used as an indicator for the treatment of sleep apnea. There is often no displaced air volume in sleep apnea due to obstruction.

One measure that is effective in obstructive sleep apnea is tracheostomy. However, this surgical intervention carries considerable morbidity and is aesthetically unacceptable to many patients. Other surgical procedures include pulling the tongue as forward as possible and surgically cutting and removing sections of the tongue and other structures which can close off the upper airway passage.

A need exists for an apparatus to treat obstructive sleep apnea without major surgical intervention. A further need exists for an apparatus to reduce a volume of a selected site in an interior of the tongue. Still a further need exists for an apparatus to reduce a volume of a selected site in an interior of the tongue without damaging the hypoglossal nerve.

SUMMARY OF THE INVENTION

Accordingly, an object of the invention is to provide an apparatus to reduce a volume of a selected site in an interior of the tongue.

5 Another object of the invention is to provide an apparatus to reduce a volume of a selected site in an interior of the tongue including an electrode and an electrode advancement device, wherein the electrode advancement member advances the electrode an advancement distance in the interior of the tongue sufficient for an electrode electromagnetic energy delivery surface to deliver electromagnetic energy to the selected tissue site and reduce a volume of the
10 selected site without damaging a hypoglossal nerve.

Yet another object of the invention is to provide an apparatus to reduce a volume of a selected site in an interior of the tongue including an electrode and an electrode advancement member, wherein the electrode advancement member advances the electrode to a placement position in the interior of the tongue so
15 that at the placement position an electrode electromagnetic energy delivery surface can deliver sufficient electromagnetic energy to reduce a volume of the selected site without damaging a hypoglossal nerve.

A further object of the invention is to provide an apparatus to reduce a volume of a selected site in an interior of the tongue with an electrode, an
20 electrode electromagnetic energy delivery surface and an electrode advancement length extending from an exterior of a handpiece to the interior of the tongue, wherein the advancement length is sufficient to position the electrode electromagnetic energy delivery surface at the selected site and deliver sufficient electromagnetic energy to reduce a volume of the selected tissue site without
25 damaging a hypoglossal nerve.

Still a further object of the invention is to provide an apparatus to reduce a volume of a selected site in an interior of the tongue that includes an electrode with a geometric shape configured to reduce a volume of the selected site without damaging a hypoglossal nerve.

30 These and other objects of the invention are achieved in an apparatus that reduces a volume of a selected site in an interior of the tongue. The apparatus

includes a handpiece and an electrode at least partially positioned in the interior of the catheter. The electrode includes an electrode electromagnetic energy delivery surface and is advance able from the interior of the handpiece into the interior of the tongue. An electrode advancement member is coupled to the electrode and configured to advance the electrode an advancement distance in the interior of the tongue. The advancement distance is sufficient for the electrode electromagnetic energy delivery surface to deliver electromagnetic energy to the selected tissue site and reduce a volume of the selected site without damaging a hypoglossal nerve and/or a surface of the tongue. A cable is coupled to the electrode.

In another embodiment, the electrode advancement member is configured to advance at least a portion of the electrode to a placement position in the interior of the tongue. At the placement position the electrode electromagnetic energy delivery surface delivers sufficient electromagnetic energy to reduce a volume of the selected site without damaging a hypoglossal nerve.

In a further embodiment, the electrode has an electrode advancement length that extends from an exterior of the catheter to the interior of the tongue. The advancement length is sufficient to position the electrode electromagnetic energy delivery surface at the selected site and deliver sufficient electromagnetic energy to reduce a volume of the selected tissue site without damaging a hypoglossal nerve.

The electrode is preferably an RF electrode coupled to an RF energy source. A cooling device can be included that is at least partially positioned in the interior of the catheter and configured to cool a selected surface of the tongue. A flow rate control device may be coupled to the cooling device to control a cooling medium flow rate through the cooling device.

An insulator is at least partially positioned around an exterior of the electrode and defines the electromagnetic energy delivery surface of the electrode. Sensors can be positioned at various locations including, at a distal end of the insulator, at the distal end of the electrode and on an exterior surface of the catheter.

In one embodiment, a first sensor is positioned at the distal end of the electrode and a second sensor positioned at the distal end of an insulator.

A feedback control device can be coupled to the electrode, the sensors and an electromagnetic energy source. Additionally, an infusion medium source
5 may be coupled to the electrode.

BRIEF DESCRIPTION OF THE FIGURES

Figure 1 is a cross-sectional view of an debulking apparatus used with the present invention.

Figure 2 is cross-sectional view illustrating the catheter and connector of
10 the debulking apparatus shown in Figure 1.

Figure 3 is a perspective view of the connector illustrated in Figure 1.

Figure 4 is a perspective view of a needle electrode associated with the debulking apparatus illustrated in Figure 1.

Figure 5 is a perspective view of a flexible needle electrode utilized with
15 the methods of the present invention.

Figure 6 illustrates the creation of ablation zones with the debulking apparatus shown in Figure 1.

Figure 7 is a cross-sectional view of the tongue with the mouth closed.

Figure 8 is a cross-sectional view of the tongue with the mouth open.

Figure 9 is a perspective view of the tongue.
20

Figure 10 is a perspective view of the dorsum of the tongue.

Figure 11 is a cross-sectional view of the tongue.

Figure 12 is a cross-sectional view of the tongue illustrating the location of the hypoglossal nerves and the creation of an ablation zone.

Figure 13 is a cross-sectional view of the tongue illustrating a plurality of
25 ablation zones.

Figure 14 is a perspective view of the ventral surface of the tongue.

Figure 15 is a cross-sectional view of the tongue.

Figure 16 is a block diagram of a feedback control system useful with the
30 methods of the present invention.

Figure 17 is a block diagram illustrating an analog amplifier, analog multiplexer and microprocessor used with the feedback control system of Figure 16.

Figure 18 is a block diagram of a temperature/impedance feedback system that can be used to control cooling medium flow rate through the catheter of Figure 1.

Figure 19 is a three dimensional graph illustrating the percent shrinkage of the tongue following RF ablation.

Figure 20 is a graph illustrating two-dimensional shrinkage of bovine tongue tissue with RF ablation.

Figure 21 is a graph illustrating three-dimensional shrinkage of bovine tongue tissue due to RF ablation.

Figure 22 is a graph illustrating percent volume change in a tongue following RF ablation.

DETAILED DESCRIPTION

Referring to Figures 1 and 2, a debulking apparatus 10, creating controlled cell necrosis and a reduction of a volume of a selected tissue site including but not limited to the tongue, lingual tonsils, and/or soft palate tissue, including but not limited to the uvula, is illustrated. Debulking apparatus 10 can be positioned so that one or more electromagnetic energy delivery devices which hereafter will be referred to as "electrodes 12". Each electrode 12 may be a needle electrode and each is introduced into an interior of the tongue through a surface of the tongue. Debulking apparatus 10 may include traumatic intubation with or without visualization, provide for the delivery of oxygen or anesthetics, and can be capable of suctioning blood or other secretions. It will be appreciated that debulking apparatus 10 is used to treat a variety of different obstructions in the body where passage of gas is restricted. One embodiment is the treatment of sleep apnea using electrodes 12 to ablate (create cell necrosis) at selected portions of the tongue, lingual tonsils and/or adenoids by the use of a variety of different energy sources including but not limited to resistive heating, RF,

microwave, ultrasound and liquid thermal jet. The preferred energy source is an RF source. In this regard, debulking apparatus 10 can be used to ablate targeted masses including but not limited to the tongue, tonsils, turbinates, soft palate tissues, hard tissue and mucosal tissue. In one embodiment, debulking apparatus 5 10 is used to ablate an interior region of the tongue, causing it to become debulked in order to increase the cross-sectional area of the airway passage. A disinfectant medium introduction member introduces a disinfectant medium in the oral cavity in order to reduce infection of the ablated body member.

Prior to debulking the tongue, a presurgical evaluation may be performed 10 including a physical examination, fiber optic pharyngoscopy, cephalometric analysis and polygraphic monitoring. The physical examination emphasizes the evaluation of the head and neck. It also includes a close examination of the nasal cavity to identify obstructing deformities of the septum and turbinate; oropharyngeal obstruction from a long, redundant soft palate or hypertrophic 15 tonsils; and hypopharyngeal obstruction from a prominent base of the tongue.

Debulking apparatus 10 includes a catheter 14, an optional handle 16 and one or more electrodes 12 extending from different ports 18 formed along a longitudinal surface of catheter 14, or from a distal end of electrode 12. Catheter 14 can be a handpiece. An electrode advancement device 20 may be 20 provided. Electrode advancement device 20 can include guide tracks or tubes 23 positioned in the interior of catheter 14. Electrodes 12 may be positioned in guide tracks 23 and advanced from the guide tracks into the interior of the tongue. Cabling is coupled to electrodes 12.

Controlled volumetric reduction of the tongue, under feedback control is 25 used to achieve an effective opening in the airway passage. A variety of different pain killing medicaments, including but not limited to Xylocaine, may be used. A digital ultrasonic measurement system can be used. The ultrasound measurement quantifies biological shape changes, provides ultrasonic transmission and reception, uses piezoelectric transducers (crystals) and provides time of flight 30 data.

A disinfectant medium introduction member 21 may be included and introduced into the oral cavity. Disinfectant medium introduction member 21 can be introduced before, after or during the introduction of debulking apparatus 10 into the oral cavity. Additionally, disinfectant medium introduction member 21 can be removed at the same time or at a different time that debulking apparatus 10 is removed from the oral cavity. Disinfectant medium introduction member 21 can be included in debulking apparatus 10, in an interior of catheter 14 or at an exterior of catheter 14, and may be an introducer with a lumen configured to introduce a disinfectant agent from a disinfectant agent source 23 into all or a selected portion of the oral cavity. Disinfectant medium introduction member 21 can be capable of movement within the oral cavity in order to provide for disinfection of all or only a portion of the oral cavity. For purposes of this disclosure, the oral cavity is that body internal environment where infectious germs may be introduced into the ablated tongue, soft tissue structure, and the like. Disinfectant medium introduction member 21 may be slideably positioned in catheter 14 or at its exterior. Alternatively, disinfectant medium introduction member 21 can be an optical fiber coupled to a light energy source, including but not limited to a UV source 25. The optical fiber can also be slideably be positioned in the oral cavity. The optical fiber is configured to provide for the selective disinfection of all or only a portion of the oral cavity and can have a variety of different distal ends to achieve this purpose.

Suitable disinfectant agents include but are not limited to Peridex, an oral rinse containing 0.12% chlorhexidine glucinate (1, 1'-hexanethylenebis[5-(p-chlorophenyl) biganide} di-D-gluconate in a base containing water, 11.6% alcohol, glycerin, PEG 40 sorbitan arisoterate, flavor, dosium saccharin, and FD&C Blue No. 1.

It will be appreciated that a variety of different disinfectants can be employed, including other electromagnetic wavelengths, and various chemical compositions. The disinfectant medium can be introduced prior to ablation, during ablation and/or after the ablation. It can be delivered continuously. The level of disinfection of the oral cavity is selectable as is the volume of the oral

cavity that is disinfected. The degree of disinfection varies. Disinfection is provided to reduce infection of the ablated body structure.

Electrodes 12 are at least partially positioned in an interior of catheter 14.

Each electrode 12 is advanced and retracted through a port 18 formed in an exterior surface of catheter 14. Electrode advancement and retraction device advances electrodes 12 out of catheter 14, into an interior of a body structure and can also provide a retraction of electrodes 12 from the interior of the body structure. Although the body structure can be any number of different structures, the body structure will hereafter be referred to as the tongue.

Electrodes 12 pierce an exterior surface of the tongue and are directed to an interior region of the tongue. Sufficient electromagnetic energy is delivered by electrodes 12 to the interior of the tongue to cause the tongue to become sufficiently ablated and debulked. Electrodes 12 can be hollow to receive a variety of different infusion mediums, including but not limited to saline.

Electrodes 12 may be limited in the distance that they can be advanced into the tongue. This is achieved with an insulation sleeve that is in a surrounding relationship to an exterior of electrode 12, a structure located on electrodes 12 which limits their advancement, or a structure coupled to catheter which limits the advancement of electrodes 12, such as a stop and the like.

Electrodes 12 can include a central lumen for receiving a variety of fluids that can be introduced into the interior of the tongue, as well as a plurality of fluid delivery ports. In one embodiment, the disinfectant agent is introduced through electrodes 12 into the interior of the selected body structure. One suitable fluid is an electrolytic solution. Instead of direct contact with tissue and electrode 12 for the delivery of thermal energy, a cooled electrolytic solution can be used to deliver the thermal energy to the tissue. The electrolytic solution may be cooled in the range of about 30 to 55 degrees C.

Catheter 14 includes a catheter tissue interface surface 22, a cooling medium inlet conduit 24 and a cooling medium exit conduit 26 extending through an interior of catheter 14. Ports 18 are formed in the exterior of catheter 14, and are preferably formed on catheter tissue interface surface 22.

Ports 18 are isolated from a cooling medium flowing in inlet and outlet conduits 24 and 26. Cooling medium inlet and exit conduits 24 and 26 are configured to provide a cooled section of catheter tissue interface surface 22 of at least 1 to 2 cm². In one embodiment, the cooled section of catheter tissue interface surface 22 is at least equal to the cross-sectional diameter of the underlying zone of ablation. In another embodiment, the cooled section of catheter tissue interface surface 22 only provides cooling to an area associated with each deployed electrode 12.

The size of the cooled section of catheter tissue interface surface 22 varies for each patient. The size is sufficient enough to minimize swelling of the tongue following the delivery of electromagnetic energy. The reduction of swelling can be 50% or greater, 75% or greater, and 90% and greater. The amount of cooling provided is sufficient to enable the patient to return home shortly after the debulking procedure is performed, and not run the risk of choking on the tongue. It has been found that by providing a sufficient level of cooling over a relatively large area, the amount of ablation in an interior region of the tongue is enhanced. By providing a sufficiently large enough cooled section of catheter tissue interface surface 22, an adenomas response is minimized.

An electromagnetic energy delivery surface 30 of electrode 12 can be adjusted by inclusion of an adjustable or non-adjustable insulation sleeve 32 (Figures 3, 4, and 5). Insulation sleeve 32 can be advanced and retracted along the exterior surface of electrode 12 in order to increase or decrease the length of the electromagnetic energy delivery surface 30. Insulation sleeve 32 can be made of a variety of materials including but not limited to nylon, polyimides, other thermoplastics and the like. The size of electromagnetic energy delivery surface 30 can be varied by other methods including but not limited to creating a segmented electrode with a plurality of electrodes that are capable of being multiplexed and individually activated, and the like.

Referring specifically to Figure 4, electrode 12 has an advancement length 33 that extends from an exterior surface of catheter 14 and is directed into

the interior of the tongue. Advancement length 33 is sufficient to position electromagnetic energy delivery surface 30 at a selected tissue site in the interior of the tongue. Electromagnetic energy delivery surface 30 is of sufficient length so that electromagnetic energy is delivered to the selected tissue site, create a
5 desired level of ablation (cell necrosis) at the selected tissue site without causing damage to the hypoglossal nerve. Electromagnetic energy delivery surface 30 is not always at the distal end of electrode 12. Insulation 32 can also be positioned at the distal end of electrode 12. In this embodiment, electromagnetic energy delivery surface 30 does not extend to the distal end of electrode 12. However,
10 electromagnetic energy delivery surface 30 still delivers sufficient electromagnetic energy to create a desired level of cell necrosis in the interior of the tongue at the selected tissue site without damaging the hypoglossal nerve and/or damage to the surface of the tongue. Additionally, only one side or a portion of a side of electrode 12 can be insulated. This also provides for an
15 electrode 12 which can be positioned throughout the tongue, including adjacent to a hypoglossal nerve. Where electrode 12 is adjacent to the hypoglossal nerve, electrode 12 is insulated.

In one embodiment, advancement length 33 is 1.2 to 1.5 cm, and the length of electromagnetic energy delivery surface 30 is 5 to 10 mm, more
20 preferably about 8 mm.

In another embodiment, advancement length 33 is insufficient to reach the hypoglossal nerve when introduced through any of the tongue surfaces, particularly the dorsum of the tongue.

Electrode advancement device 20 is configured to advance at least a
25 portion of each electrode 12 to a placement position in the interior of the tongue. Electrode advancement 20 can also be configured to retract each electrode 12. At the placement position, electrode electromagnetic energy delivery surface delivers sufficient electromagnetic energy to reduce a volume of the selected site without damaging a hypoglossal nerve and/or a surface of the tongue. In one
30 embodiment, electrode advancement and retraction device 20, with or without guide tracks 23, directs the delivery of an electrode 12 from catheter 14 into the

interior of the tongue at an angle of 60 to 90 degrees relative to a longitudinal axis of catheter 14, and preferably about 70 degrees.

Each electrode 12 has a geometric shape, including but not limited to a curved configuration that includes one or more insulated surfaces, either partially insulated on one side, at a proximal end, at a distal end, and the like, that is configured to reduce the volume of the selected tissue site without damaging a hypoglossal nerve. In one embodiment, electrode 12 is introduced through any tongue surface and is configured so that a section of electrode 12 which may be positioned close to the hypoglossal nerve is provided with insulation 32. As previously noted, insulation 32 can be positioned at different sites of electrode 12.

Handle 16 is preferably made of an insulating material. Electrodes 12 are made of a conductive material such as stainless steel. Additionally, electrodes 12 can be made of a shaped memory metal, such as nickel titanium, commercially available from Raychem Corporation, Menlo Park, California. In one embodiment, only a distal end of electrode 12 is made of the shaped memory metal in order to effect a desired deflection. When introduced into the oral cavity, catheter 14 can be advanced until a patient's gag response is initiated. Catheter 14 is then retracted back to prevent patient's gagging. The distal end of electrode 12 can be semi-curved. The distal end can have a geometry to conform to an exterior of the tongue.

In one embodiment of the invention catheter 14 is a handpiece and shall for purposes of this invention catheter 14 shall be referred to as ("handpiece 14"). In this embodiment, a separate handle 16 is not necessary. Debulking apparatus 10 is used to treat an interior region of the tongue. Handpiece 14 has a distal end that is sized to be positioned within an oral cavity. Electrode 12 is at least partially positioned within an interior of handpiece 14. Electrode 14 includes an electromagnetic energy delivery surface 30. Electrode advancement member 20 is coupled to electrode 12 and calibrated to advance electrode 12 from handpiece 20, including but not limited to a distal end of handpiece 20, into the interior of the tongue when handpiece 20 is positioned adjacent to a surface

of the tongue. Electrode 20 is advanced an advancement distance 33 from handpiece 20 of sufficient length to treat the interior region of the tongue with electromagnetic energy without damaging the hypoglossal nerve or the surface of the tongue.

5 Catheter 14 can be malleable in order to conform to the surface of the tongue when a selected ablation target site is selected. An encapsulated soft metal, such as copper, or an annealed metal/plastic material can be used to form malleable catheter 14. All or a portion of catheter 14 may be malleable or made of a shaped memory metal.

10 For many applications it is desirable for a distal end 14' of catheter 14 to be deflectable. This can be achieved mechanically or with the use of memory metals. A steering wire, or other mechanical structure, can be attached to either the exterior or interior of distal end 14'. In one embodiment, a deflection knob located on handle 16 is activated by the physician causing a steering wire to
15 tighten. This imparts a retraction of distal end 14', resulting in its deflection. It will be appreciated that other mechanical devices can be used in place of the steering wire. The deflection may be desirable for tissue sites with difficult access.

Handle 6 can comprise a connector 34 coupled to retraction and
20 advancement device 20. Connector 34 provides a coupling of electrodes 12 to power, feedback control, temperature and/or imaging systems. An RF/temperature control block 36 can be included.

In one embodiment, the physician moves retraction and advancement device 20 in a direction toward a distal end of connector 34. Electrodes 12 can
25 be spring loaded. When electrode advancement device 20 is moved back, springs cause selected electrodes 12 to advance out of catheter 14.

One or more cables 38 couple electrodes 12 to an electromagnetic energy source 40. A variety of energy sources 40 can be used with the present invention to transfer electromagnetic energy to the interior of a body structure,
30 including but not limited to RF, microwave, ultrasound, coherent light and thermal transfer. Preferably, energy source 40 is a RF generator. When a RF

energy source is used, the physician can activate RF energy source 40 by the use of a foot switch (not shown) coupled to RF energy source 40.

One or more sensors 42 may be positioned on an interior or exterior surface of electrode 12, insulation sleeve 32, or be independently inserted into the interior of the body structure. Sensors 42 permit accurate measurement of temperature at a tissue site in order to determine, (i) the extent of ablation, (ii) the amount of ablation, (iii) whether or not further ablation is needed, and (iv) the boundary or periphery of the ablated geometry. Further, sensors 42 prevent non-targeted tissue from being destroyed or ablated.

Sensors 42 are of conventional design, including but not limited to thermistors, thermocouples, resistive wires, and the like. Suitable sensors 42 include a T type thermocouple with copper constantene, J type, E type, K type, fiber optics, resistive wires, thermocouple IR detectors, and the like. It will be appreciated that sensors 42 need not be thermal sensors.

Sensors 42 measure temperature and/or impedance to permit ablation monitoring. This reduces damage to tissue surrounding the targeted ablation mass. By monitoring the temperature at various points within the interior of the body structure the periphery of ablation can be ascertained and it is possible to determine when the ablation is completed. If at any time sensor 42 determines that a desired ablation temperature is exceeded, then an appropriate feedback signal is received at energy source 40 and the amount of energy delivered is regulated.

Debulking apparatus 10 can include visualization capability including but not limited to a viewing scope, an expanded eyepiece, fiber optics, video imaging, and the like.

Additionally, ultrasound imaging can be used to position the electrodes 12 and/or determine the amount of ablation. One or more ultrasound transducers 44 can be positioned in or on electrode 12, catheter 14, or on a separate device. An imaging probe may also be used internally or externally to the selected tissue site. A suitable imaging probe is Model 21362, manufactured

and sold by Hewlett Packard Company. Each ultrasound transducer 44 is coupled to an ultrasound source (not shown).

With reference now to Figure 6 catheter 14 is shown as being introduced into the oral cavity and multiple RF electrodes 12 are advanced into the interior of the tongue creating different ablation zones 46. Debulking apparatus 10 can be operated in either bipolar or monopolar modes. In Figure 6, electrodes 12 are operated in the bipolar mode, creating sufficient ablation zones 46 to debulk the tongue without affecting the hypoglossal nerves and creating a larger airway passage. With this debulking, the back of the tongue moves in a forward direction away from the air passageway. The result is an increase in the cross-sectional diameter of the air passageway.

Debulking apparatus 10 can also be operated in the monopolar mode. A groundpad can be positioned in a convenient place such as under the chin. A single electrode 12 is positioned in the tongue to create a first ablation zone 46. Electrode 12 can then be retracted from the interior of the tongue, catheter 14 moved, and electrode 12 is then advanced from catheter 14 into another interior section of the tongue. A second ablation zone 46 is created. This procedure can be completed any number of times to form different ablation regions in the interior of the tongue. More than one electrode 12 can be introduced into the tongue and operated in the bipolar mode. Electrodes 12 are then repositioned in the interior of the tongue any number of times to create a plurality of connecting or non-connecting ablation zones 46.

Referring now to Figures 7 through 15, various anatomical views of the tongue and other structures are illustrated. The different anatomical structures are as follows: the genioglossus muscle, or body of the tongue is denoted as 48; the geniohyoid muscle is 50; the mylohyoid muscle is 52; the hyoid bone is 54; the tip of the tongue is 56; the ventral surface of the tongue is denoted as 58; the dorsum of the tongue is denoted as 60; the inferior dorsal of the tongue is denoted as 62; the reflex of the vallecula is 64; the lingual follicles are denoted as 66; the uvula is 68; the adenoid area is 70; the lateral border of the tongue is 72; the circumvallate papilla is 74, the palatine tonsil is 76; the pharynx is 78; the

redundant pharyngeal tissue is 80; the foramen cecum is 82; the hypoglossal nerve is 84, and the lingual frenum of the tongue is 86.

Dorsum 60 is divided into an anterior 2/3 and inferior dorsal 62. The delineation is determined by circumvallate papilla 74 and foramen cecum 82. Inferior dorsal 62 is the dorsal surface inferior to circumvallate papilla 74 and superior reflex of the vallecula 64. Reflex of the vallecula 64 is the deepest portion of the surface of the tongue contiguous with the epiglottis. Lingual follicles 66 comprise the lingual tonsil.

Catheter 14 can be introduced through the nose or through the oral cavity. Electrodes 12 can be inserted into an interior of the tongue through dorsum surface 60, inferior dorsal surface 62, ventral surface 58, tip 56 or geniohyoid muscle 50. Additionally, electrodes may be introduced into an interior of lingual follicles 66 and into adenoid area 70. Once electrodes 12 are positioned, insulation sleeve 32 may be adjusted to provided a desired electromagnetic energy delivery surface 30 for each electrode 12.

Ablation zones 46 are created without damaging hypoglossal nerves 84. This creates a larger air way passage and provides a treatment for sleep apnea.

In all instances, the positioning of electrodes 12, as well as the creation of ablation zones 46 is such that hypoglossal nerves 84 are not ablated or damaged. The ability to swallow and speak is not impaired.

Electrodes may be positioned on dorsum surface 60 of the tongue. The first electrode is positioned 0.5 cm proximal to the circumvallate papilla. The other electrodes are spaced 1.6 cm apart and are 1 cm off a central axis of the tongue. In one embodiment, 465 MHz RF was applied. The temperature at the distal end of electrode 12 was about 100 degrees C. The temperature at the distal end of the insulation sleeve 32 was about 60 degrees C. In another embodiment, the temperature at the distal end of insulation sleeve 32 was 43 degrees C and above. RF energy can be applied as short duration pulses with low frequency RF. Precise targeting of a desired ablation site is achieved. One or more electrodes 12 may be used to create volumetric three-dimensional ablation. A variety of ablation geometries are possible, including but not limited

to rectilinear, polyhedral, redetermined shapes, symmetrical and non-symmetrical.

Referring now to Figures 16 and 17 an open or closed loop feedback system couples sensors 42 to energy source 40. The temperature of the tissue, or of electrode 12 is monitored, and the output power of energy source 40
5 adjusted accordingly. Additionally, the level of disinfection in the oral cavity can be monitored. The physician can, if desired, override the closed or open loop system. A microprocessor can be included and incorporated in the closed or open loop system to switch power on and off, as well as modulate the power.
10 The closed loop system utilizes a microprocessor 88 to serve as a controller, watch the temperature, adjust the RF power, look at the result, refeed the result, and then modulate the power.

With the use of sensors 42 and the feedback control system a tissue adjacent to RF electrodes 12 can be maintained at a desired temperature for a
15 selected period of time without impeding out. Each RF electrode 12 is connected to resources which generate an independent output for each RF electrode 12. An output maintains a selected energy at RF electrodes 12 for a selected length of time.

Current delivered through RF electrodes 12 is measured by current
20 sensor 90. Voltage is measured by voltage sensor 92. Impedance and power are then calculated at power and impedance calculation device 94. These values can then be displayed at user interface and display 96. Signals representative of power and impedance values are received by a controller 98.

A control signal is generated by controller 98 that is proportional to the
25 difference between an actual measured value, and a desired value. The control signal is used by power circuits 100 to adjust the power output in an appropriate amount in order to maintain the desired power delivered at respective RF electrodes 12.

In a similar manner, temperatures detected at sensors 42 provide
30 feedback for maintaining a selected power. The actual temperatures are measured at temperature measurement device 102, and the temperatures are

displayed at user interface and display 96. A control signal is generated by controller 98 that is proportional to the difference between an actual measured temperature, and a desired temperature. The control signal is used by power circuits 100 to adjust the power output in an appropriate amount in order to maintain the desired temperature delivered at the respective sensor. A multiplexer can be included to measure current, voltage and temperature, at the numerous sensors 42, and energy can be delivered to RF electrodes 12 in monopolar or bipolar fashion.

Controller 98 can be a digital or analog controller, or a computer with software. When controller 98 is a computer it can include a CPU coupled through a system bus. On this system can be a keyboard, a disk drive, or other non-volatile memory systems, a display, and other peripherals, as are known in the art. Also coupled to the bus is a program memory and a data memory.

User interface and display 96 includes operator controls and a display. Controller 98 can be coupled to imaging systems, including but not limited to ultrasound, CT scanners, X-ray, MRI, mammographic X-ray and the like. Further, direct visualization and tactile imaging can be utilized.

The output of current sensor 90 and voltage sensor 92 is used by controller 98 to maintain a selected power level at RF electrodes 12. The amount of RF energy delivered controls the amount of power. A profile of power delivered can be incorporated in controller 98, and a preset amount of energy to be delivered can also be profiled.

Circuitry, software and feedback to controller 98 result in process control, and the maintenance of the selected power that is independent of changes in voltage or current, and are used to change, (i) the selected power, (ii) the duty cycle (on-off and wattage), (iii) bipolar or monopolar energy delivery, and (iv) infusion medium delivery, including flow rate and pressure. These process variables are controlled and varied, while maintaining the desired delivery of power independent of changes in voltage or current, based on temperatures monitored at sensors 42.

Current sensor 90 and voltage sensor 92 are connected to the input of an analog amplifier 104. Analog amplifier 104 can be a conventional differential amplifier circuit for use with sensors 42. The output of analog amplifier 104 is sequentially connected by an analog multiplexer 106 to the input of A/D converter 108. The output of analog amplifier 104 is a voltage which represents the respective sensed temperatures. Digitized amplifier output voltages are supplied by A/D converter 108 to microprocessor 88. Microprocessor 88 may be a type 68HCII available from Motorola. However, it will be appreciated that any suitable microprocessor or general purpose digital or analog computer can be used to calculate impedance or temperature.

Microprocessor 88 sequentially receives and stores digital representations of impedance and temperature. Each digital value received by microprocessor 88 corresponds to different temperatures and impedances.

Calculated power and impedance values can be indicated on user interface and display 96. Alternatively, or in addition to the numerical indication of power or impedance, calculated impedance and power values can be compared by microprocessor 88 with power and impedance limits. When the values exceed predetermined power or impedance values, a warning can be given on user interface and display 96, and additionally, the delivery of RF energy can be reduced, modified or interrupted. A control signal from microprocessor 88 can modify the power level supplied by energy source 40.

Figure 18 illustrates a block diagram of a temperature/impedance feedback system that can be used to control cooling medium flow rate through catheter 14. Electromagnetic energy is delivered to electrode 12 by energy source 44, and applied to tissue. A monitor 110 ascertains tissue impedance, based on the energy delivered to tissue, and compares the measured impedance value to a set value. If the measured impedance exceeds the set value a disabling signal 112 is transmitted to energy source 40, ceasing further delivery of energy to electrode 12. If measured impedance is within acceptable limits, energy continues to be applied to the tissue. During the application of energy to tissue sensor 42 measures the temperature of tissue and/or electrode 12. A comparator

114 receives a signal representative of the measured temperature and compares this value to a pre-set signal representative of the desired temperature. Comparator 114 sends a signal to a flow regulator 116 representing a need for a higher cooling medium flow rate, if the tissue temperature is too high, or to maintain the flow rate if the temperature has not exceeded the desired temperature.

EXAMPLE 1

Debulking apparatus 10 was used to determine two-dimensional shrinkage of a bovine. RF volumetric reduction was achieved using a single needle electrode. Four mature ultrasonic crystals were positioned to form a square. Measurements were taken at control and post volumetric reduction at 15 watts initially with a 13% volumetric reduction, and 15 watts for 4 hours with an additional 4% volumetric reduction. A total 17% volumetric reduction was achieved.

EXAMPLE 2

Debulking apparatus 10 was used to determine three-dimensional shrinkage of a bovine tongue. RF volumetric reduction was achieved with a single needle electrode with eight miniature ultrasonic crystals, creating a cube. Application of 16 watts initially produced a 17% volumetric reduction of the tongue, 25 watts applied initially produced a 25% volumetric reduction, and 25 watts after hours produced an additional 4% reduction, for a total volumetric reduction of 29%.

EXAMPLE 3

A 35% volumetric reduction was achieved in porcine *in vivo*, with three dimensional gross at 20 watts initial application.

Referring now to Figure 19, ablation volume dimensions were measured with a multidimensional digital sonomicrometry. An average decrease in the Z direction was 20%, and volume shrinkage was 26%. Three-dimensional shrinkage of tongue tissue due to *in vivo* RF ablation with the needle, ablation

with 20 Watts) is presented in Figure 20. Control volume before ablation is compared with a post-ablation volume.

Figure 20 illustrates two-dimensional shrinkage of a bovine tongue tissue due to RF ablation with a needle electrode. The before and after ablation results are illustrated.

Figure 21 illustrates in graph form ablation at 16 Watts resulted in a 17% volume shrinkage of the tissue in post-ablation verses control. Ablation at 25 watts resulted in a 25% volume shrinkage after ablation. An additional 4% area shrinkage was obtained after in long-term post ablation (4 hours) verses post-ablation.

Figure 22 illustrates a percent volume change after RF ablation. 16 Watts, ablation at 16 Watts for 20 minutes; 25 Watts, ablation at 25 Watts for 20 minutes; 25 Watts (4 hours), and long tern post ablation (4 hours after 25 Watts ablation).

The foregoing description of a preferred embodiment of the invention has been presented for purposes of illustration and description. It is not intended to be exhaustive or to limit the invention to the precise forms disclosed. Obviously, many modifications and variations will be apparent to practitioners skilled in this art. It is intended that the scope of the invention be defined by the following claims and their equivalents.

What is claimed is:

CLAIMS

1. An apparatus to reduce a volume of a selected site in an interior of the tongue, comprising:
a handpiece;
5 an electrode at least partially positioned in the interior of the handpiece, the electrode including an electrode electromagnetic energy delivery surface and advance able from the interior of the handpiece into the interior of the tongue;
an electrode advancement member coupled to the electrode and configured to advance the electrode an advancement distance in the interior of
10 the tongue, wherein the advancement distance is sufficient for the electrode electromagnetic energy delivery surface to deliver electromagnetic energy to the selected tissue site and reduce a volume of the selected site without damaging a hypoglossal nerve; and
a cable coupled to the electrode.
- 15 2. The apparatus of claim 1, wherein the electrode is an RF electrode.
3. The apparatus of claim 2, further comprising:
an RF energy source coupled to the RF electrode.
4. The apparatus of claim 1, further comprising:
20 a cooling device at least partially positioned in the interior of the handpiece and configured to cool a surface of the tongue.
5. The apparatus of claim 4, further comprising:
a flow rate control device coupled to the cooling device and configured to control a cooling medium flow rate through the cooling device.
- 25 6. The apparatus of claim 1, further comprising:

an insulator at least partially positioned around an exterior of the electrode.

7. The apparatus of claim 6, further comprising:
a sensor positioned at a distal end of the insulator.

5 8. The apparatus of claim 1, further comprising:
a sensor positioned at a distal end of the electrode.

9. The apparatus of claim 1, further comprising:
a sensor positioned on an exterior of the handpiece.

10 10. The apparatus of claim 1, further comprising:
a first sensor positioned at a distal end of the electrode and a second
sensor positioned at a distal end of an insulator, wherein the insulator is at least
partially positioned around an exterior of the electrode.

15 11. The apparatus of claim 1, further comprising:
a feedback control means coupled to the electrode, a sensor and an RF
energy source.

12. The apparatus of claim 1, further comprising:
an infusion medium source coupled to the electrode.

20 13. An apparatus to reduce a volume of a selected site in an interior
of the tongue, comprising:
a handpiece;
an electrode at least partially positioned in the interior of the handpiece,
the electrode including an electrode electromagnetic energy delivery surface and
advance able from the interior of the handpiece into the interior of the tongue;

an electrode advancement and retraction member coupled to the electrode and configured to advance at least a portion of the electrode to a placement position in the interior of the tongue, wherein at the placement position the electrode electromagnetic energy delivery surface delivers sufficient electromagnetic energy to reduce a volume of the selected site without damaging a hypoglossal nerve; and

5 a cable coupled to the electrode.

14. The apparatus of claim 13, wherein the electrode advancement and retraction member further comprises:

10 a guide channel configured to receive the electrode in at least a portion of the interior of the handpiece and configured to guide an advancement direction of the electrode from the handpiece into the interior of the tongue.

15. The apparatus of claim 13, wherein the electrode is an RF electrode.

16. The apparatus of claim 14, further comprising:

15 an RF energy source coupled to the RF electrode.

17. The apparatus of claim 13, further comprising:

a cooling device at least partially positioned in the interior of the handpiece and configured to cool a surface of the tongue.

18. The apparatus of claim 17, further comprising:

20 a flow rate control device coupled to the cooling device and configured to control a cooling medium flow rate through the cooling device.

19. The apparatus of claim 13, further comprising:

an insulator at least partially positioned around an exterior of the electrode.

25

20. The apparatus of claim 19, further comprising:
a sensor positioned at a distal end of the insulator.
21. The apparatus of claim 13, further comprising:
a sensor positioned at a distal end of the electrode.
- 5 22. The apparatus of claim 13, further comprising:
a sensor positioned on an exterior of the handpiece.
23. The apparatus of claim 13, further comprising:
a first sensor positioned at a distal end of the electrode and a second
sensor positioned at a distal end of an insulator, wherein the insulator is at least
10 partially positioned around an exterior of the electrode.
24. The apparatus of claim 13, further comprising:
a feedback control means coupled to the electrode, a sensor and an RF
energy source.
- 15 25. The apparatus of claim 13, further comprising:
an infusion medium source coupled to the electrode.
26. An apparatus to reduce a volume of a selected site in an interior
of the tongue, comprising:
a handpiece;
20 an electrode at least partially positioned in the interior of the handpiece,
the electrode including an electrode electromagnetic energy delivery surface and
an electrode advancement length extending from an exterior of the handpiece to
the interior of the tongue, wherein the advancement length is sufficient to
position the electrode electromagnetic energy delivery surface at the selected site
25 and deliver sufficient electromagnetic energy to reduce a volume of the selected
tissue site without damaging a hypoglossal nerve;

an electrode advancement and retraction member coupled to the electrode and configured to advance and retract at least a portion of the electrode; and
a cable coupled to the electrode.

5 27. The apparatus of claim 26, wherein the electrode is an RF electrode.

28. The apparatus of claim 27, further comprising:
an RF energy source coupled to the RF electrode.

10 29. The apparatus of claim 26, further comprising:
a cooling device at least partially positioned in the interior of the handpiece and configured to cool a surface of the tongue.

30. The apparatus of claim 29, further comprising:
a flow rate control device coupled to the cooling device and configured to control a cooling medium flow rate through the cooling device.

15 31. The apparatus of claim 26, further comprising:
an insulator at least partially positioned around an exterior of the electrode.

32. The apparatus of claim 31, further comprising:
a sensor positioned at a distal end of the insulator.

20 33. The apparatus of claim 26, further comprising:
a sensor positioned at a distal end of the electrode.

34. The apparatus of claim 26, further comprising:
a sensor positioned on an exterior of the handpiece.

35. The apparatus of claim 26, further comprising:

a first sensor positioned at a distal end of the electrode and a second sensor positioned at a distal end of an insulator, wherein the insulator is at least partially positioned around an exterior of the electrode.

5

36. The apparatus of claim 26, further comprising:

a feedback control means coupled to the electrode, a sensor and an RF energy source.

37. The apparatus of claim 26, further comprising:

10 an infusion medium source coupled to the electrode.

38. An apparatus to reduce a volume of a selected site in an interior of the tongue, comprising:

a handpiece;

15 an electrode at least partially positioned in the interior of the handpiece and advance able from the interior of the handpiece into the interior of the tongue, wherein the electrode has a geometric shape configured to reduce a volume of the selected site without damaging a hypoglossal nerve;

20 an electrode advancement and retraction member coupled to the electrode and configured to advance and retract at least a portion of the electrode; and

a cable coupled to the electrode.

39. The apparatus of claim 38, wherein the electrode is an RF electrode.

40. The apparatus of claim 39, further comprising:

25 an RF energy source coupled to the RF electrode.

41. The apparatus of claim 38, further comprising:

a cooling device at least partially positioned in the interior of the handpiece and configured to cool a surface of the tongue.

42. The apparatus of claim 41, further comprising:
a flow rate control device coupled to the cooling device and configured
5 to control a cooling medium flow rate through the cooling device.

43. The apparatus of claim 38, further comprising:
an insulator at least partially positioned around an exterior of the
electrode.

44. The apparatus of claim 43, further comprising:
10 a sensor positioned at a distal end of the insulator.

45. The apparatus of claim 38, further comprising:
a sensor positioned at a distal end of the electrode.

46. The apparatus of claim 38, further comprising:
a sensor positioned on an exterior of the handpiece.

47. The apparatus of claim 38, further comprising:
a first sensor positioned at a distal end of the electrode and a second
15 sensor positioned at a distal end of an insulator, wherein the insulator is at least
partially positioned around an exterior of the electrode.

48. The apparatus of claim 38, further comprising:
20 a feedback control means coupled to the electrode, a sensor and an RF
energy source.

49. The apparatus of claim 38, further comprising:
an infusion medium source coupled to the electrode.

50. An apparatus to reduce a volume of a selected site in an interior of the tongue, comprising:

a handpiece; and

an electrode at least partially positioned in the interior of the handpiece,
5 the electrode including an electrode electromagnetic energy delivery surface and
an electrode advancement length extending from an exterior of the handpiece to
the interior of the tongue, wherein the advancement length is sufficient to
position the electrode electromagnetic energy delivery surface at the selected site
and deliver sufficient electromagnetic energy to reduce a volume of the selected
10 tissue site without damaging a hypoglossal nerve.

1/17

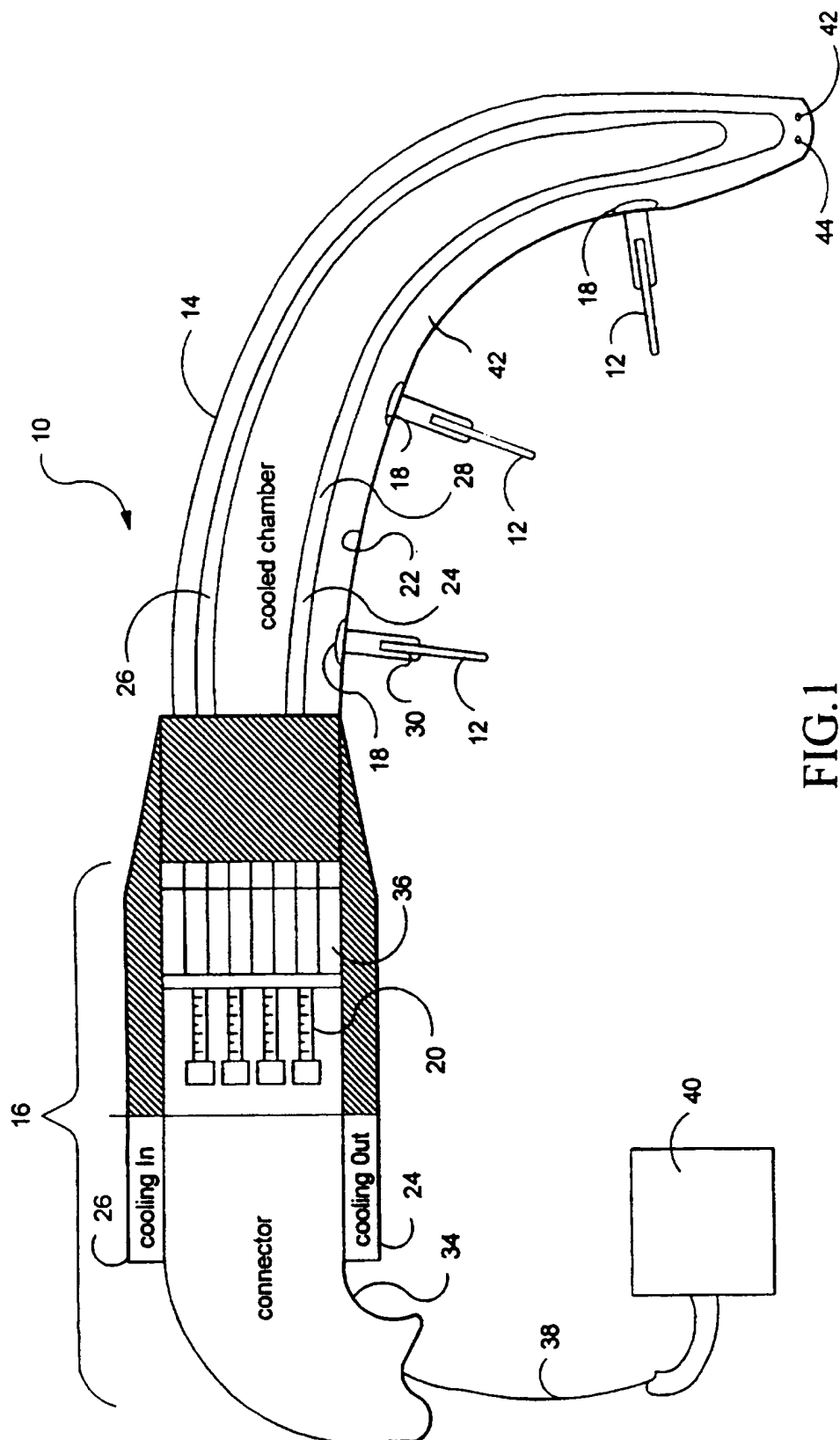


FIG. 1

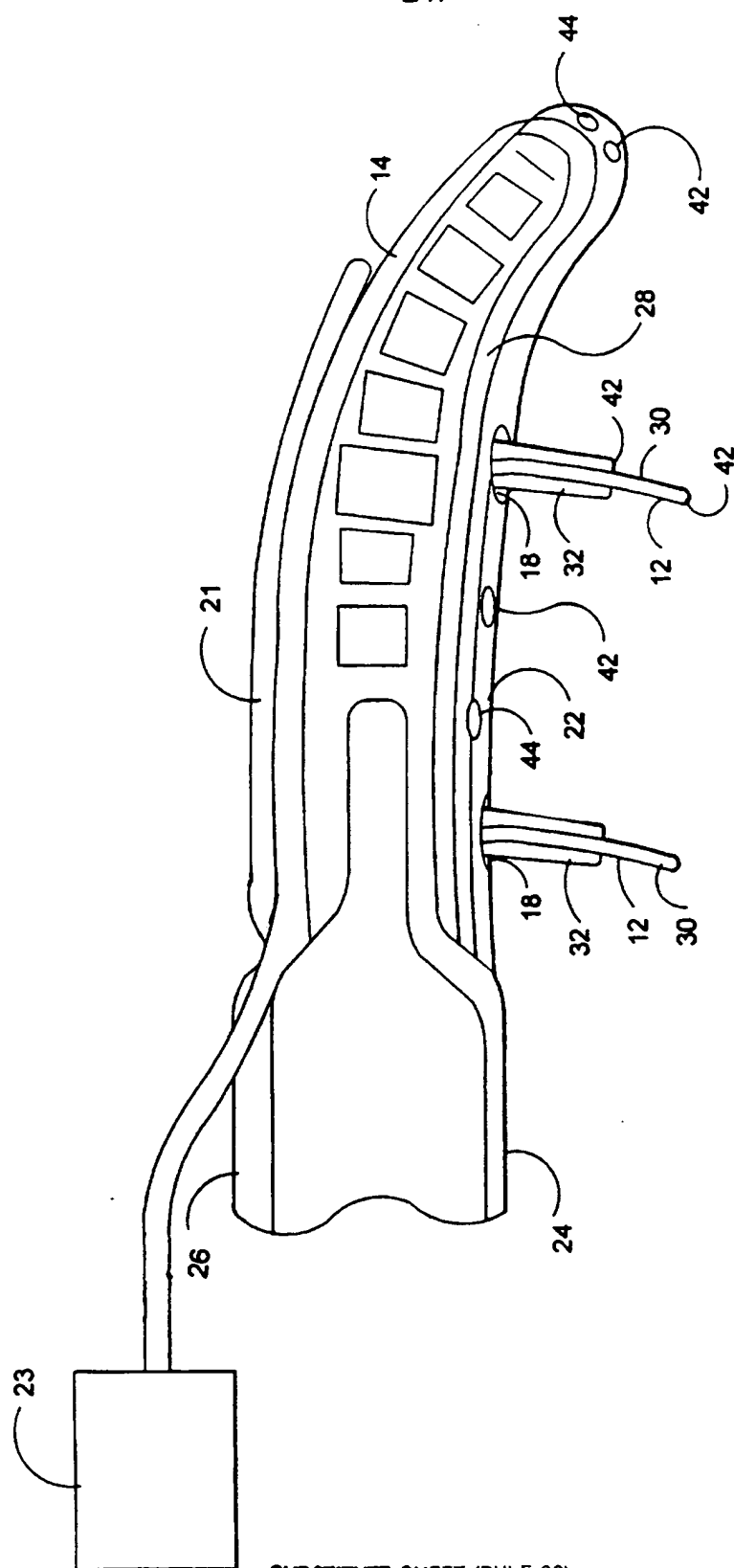


FIG. 2

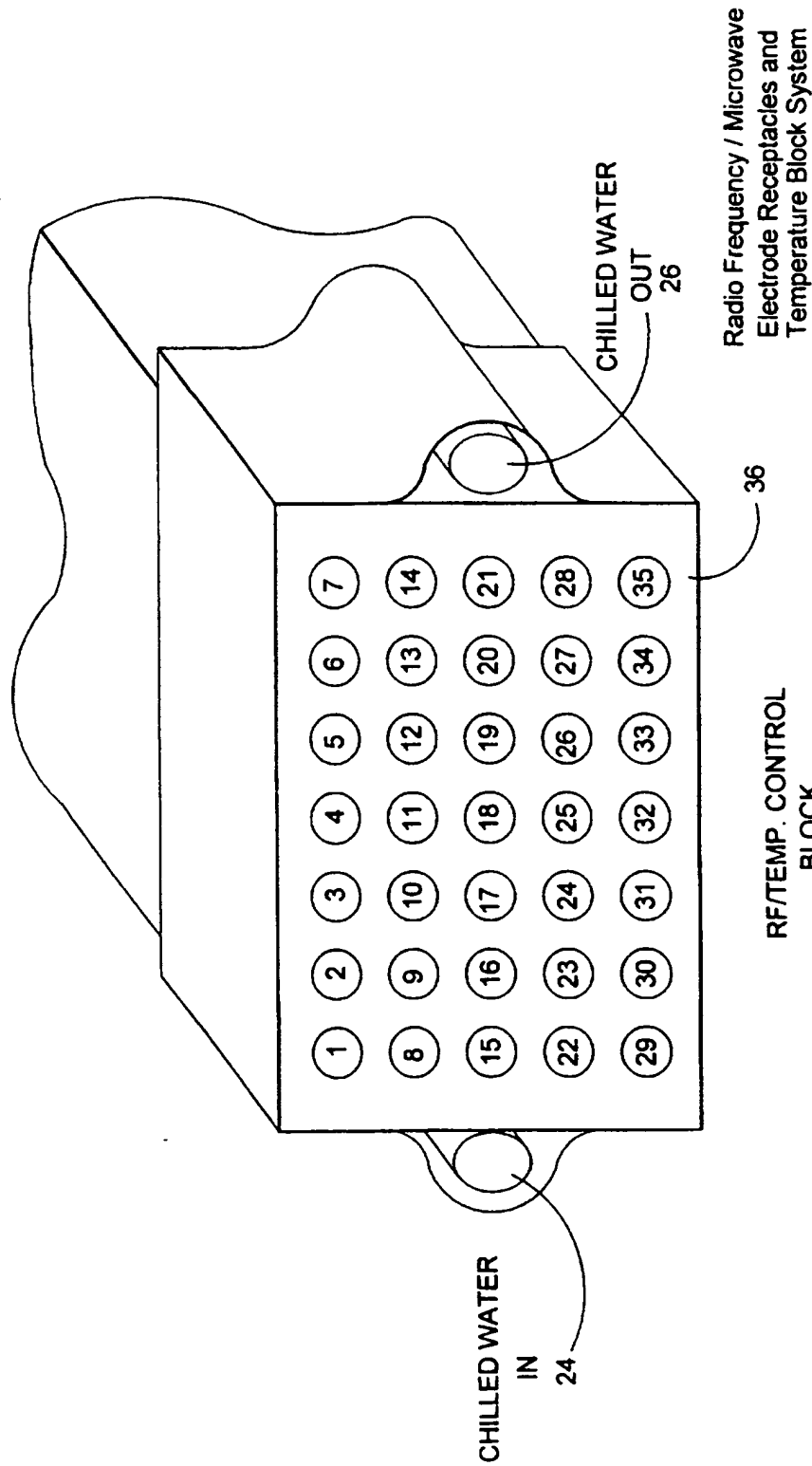


FIG.3

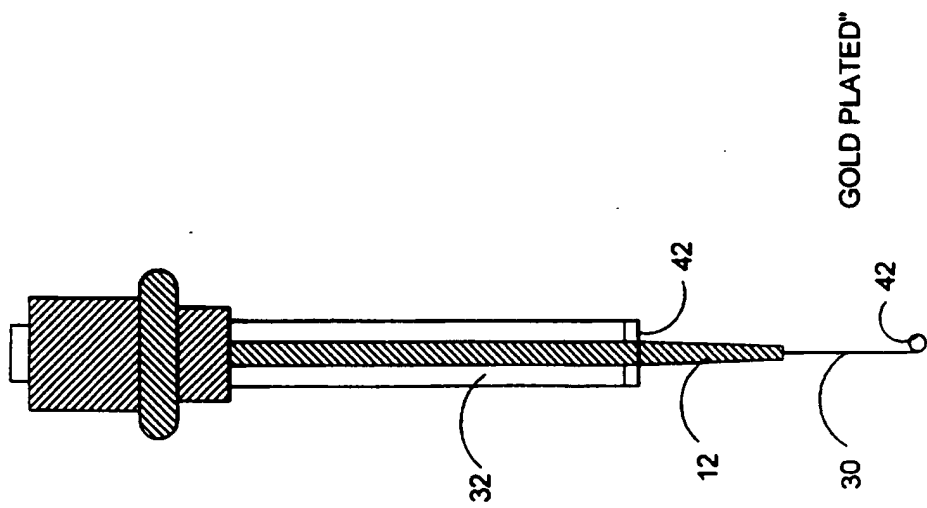


FIG. 4

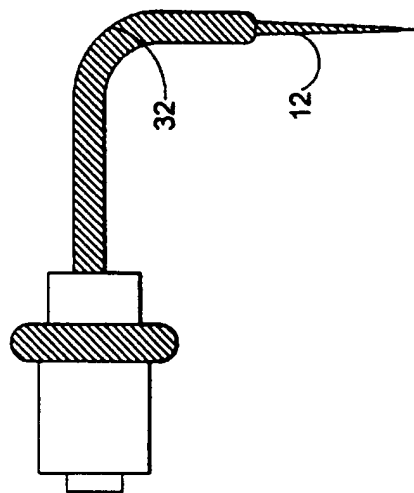


FIG. 5

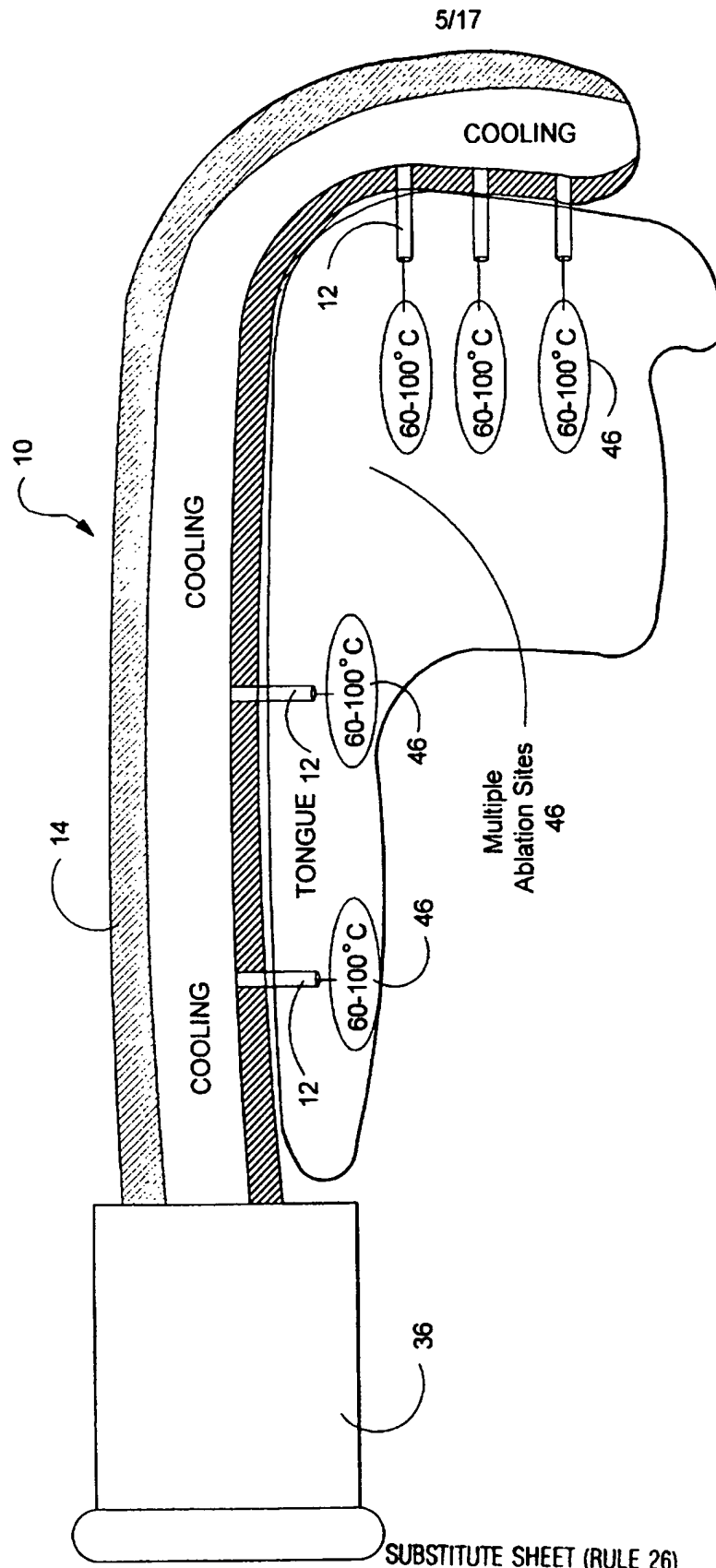
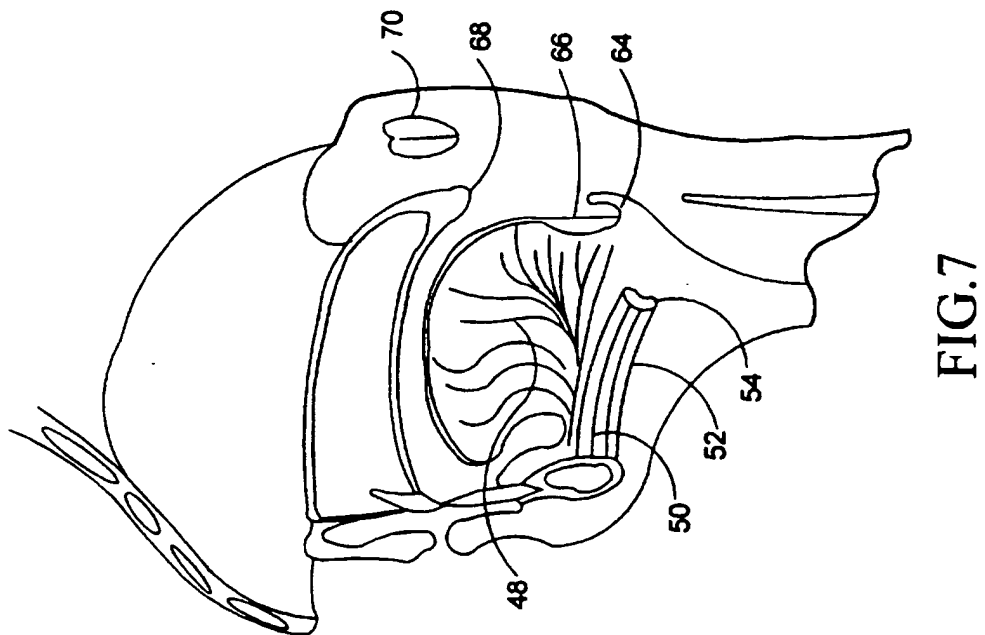
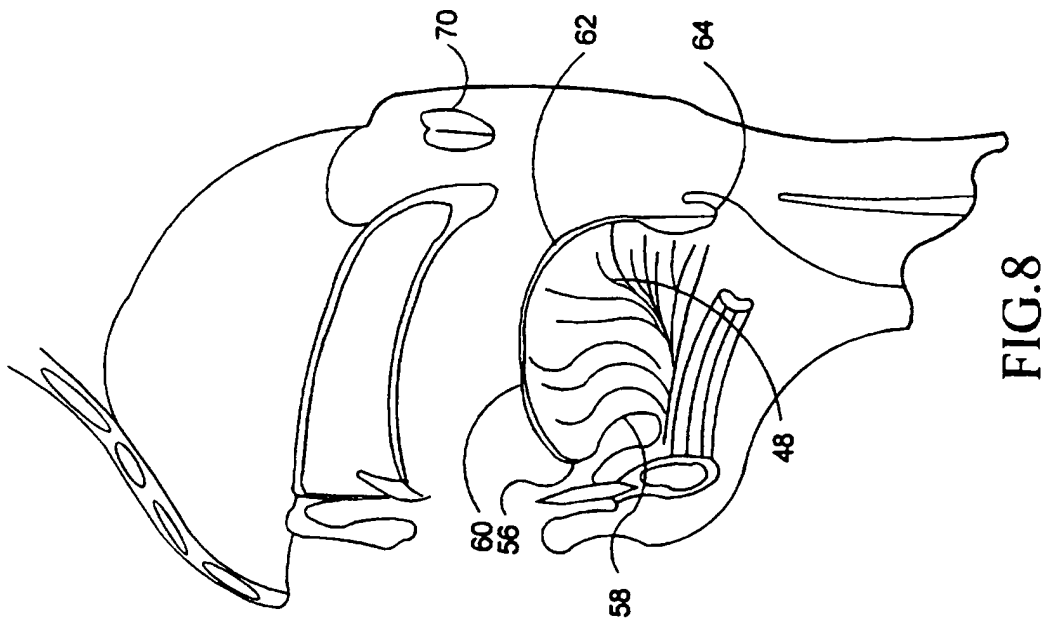


FIG. 6

6/17



SUBSTITUTE SHEET (RULE 26)

7/17

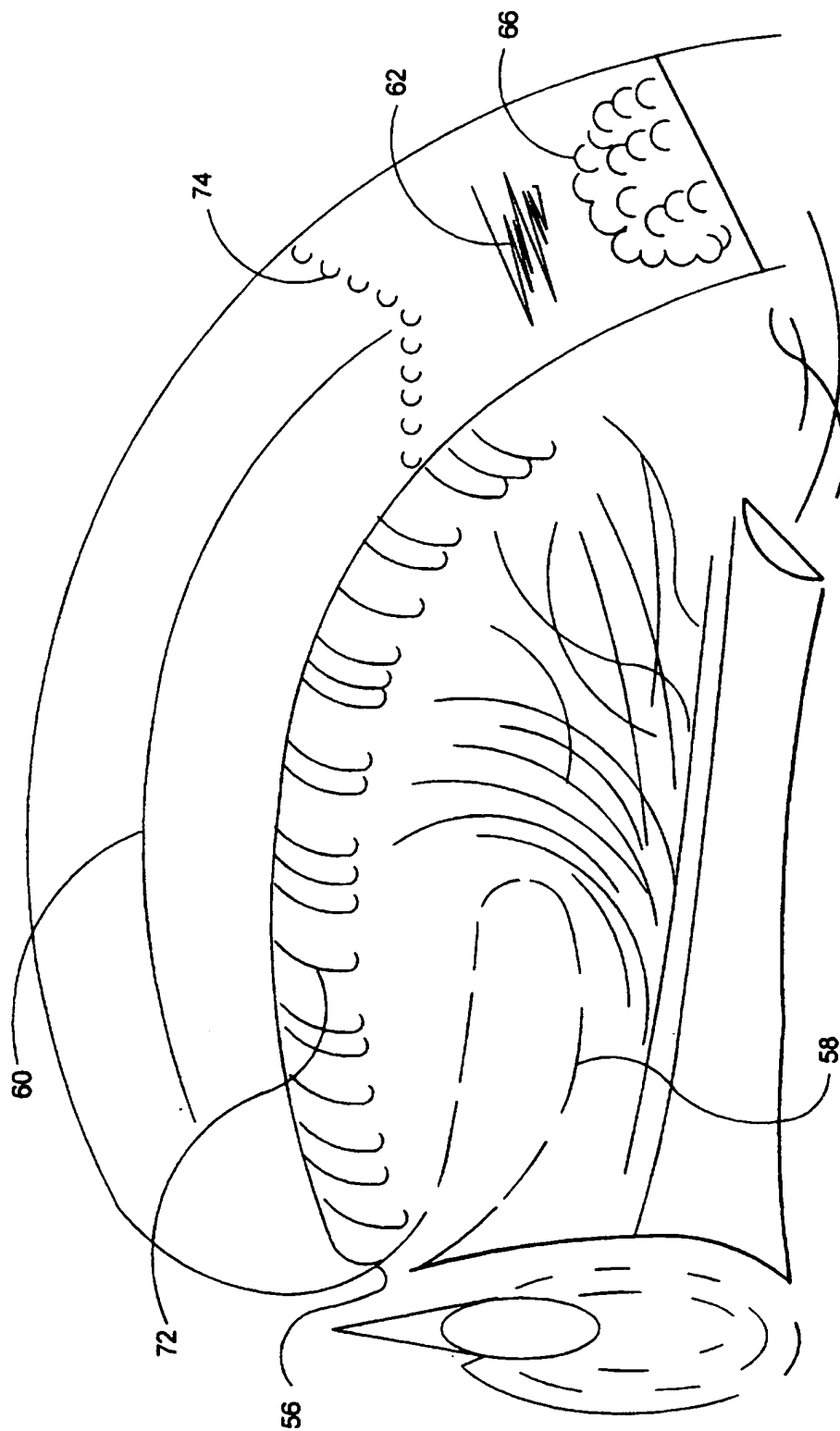


FIG. 9

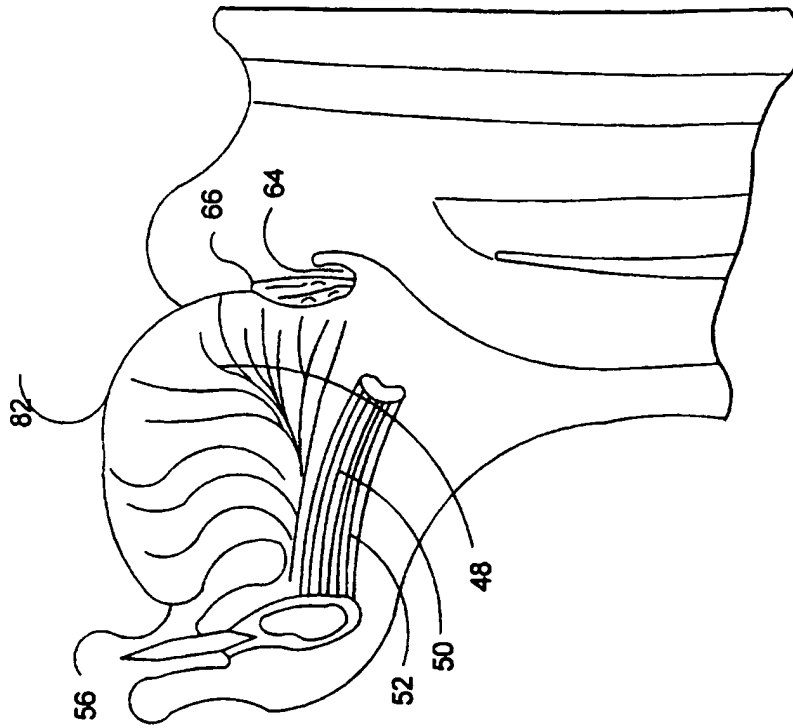


FIG.11

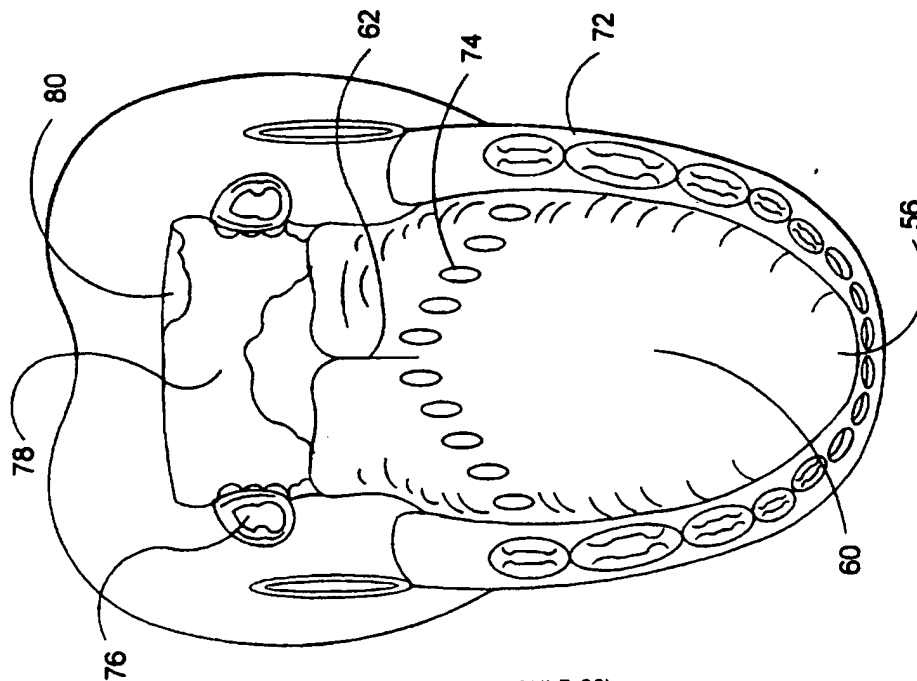


FIG.10

9/17

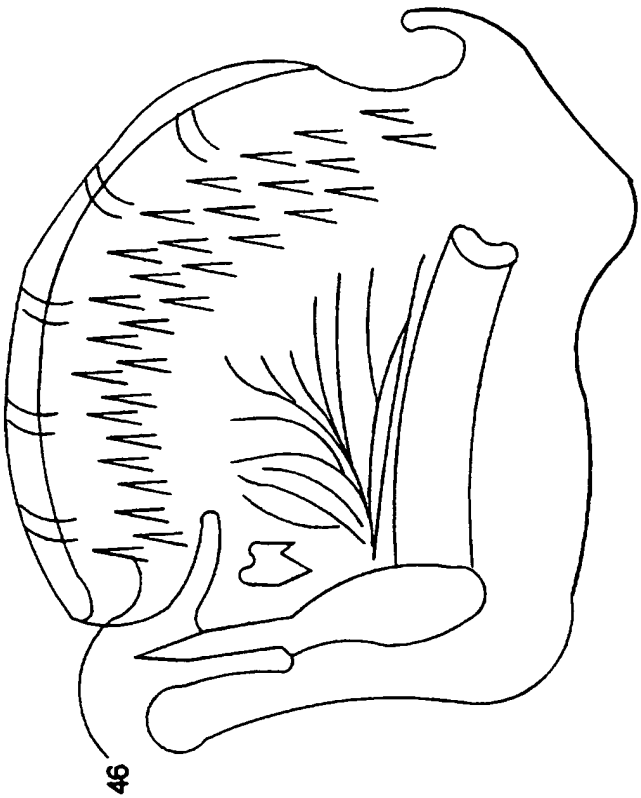


FIG. 13

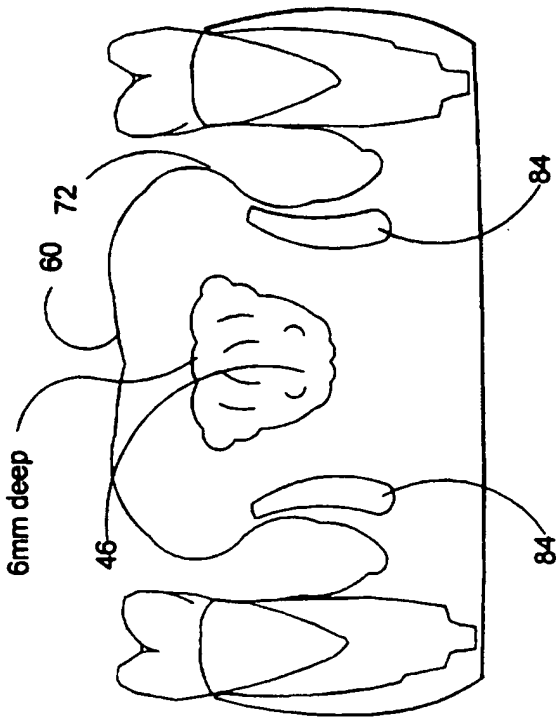


FIG. 12

10/17

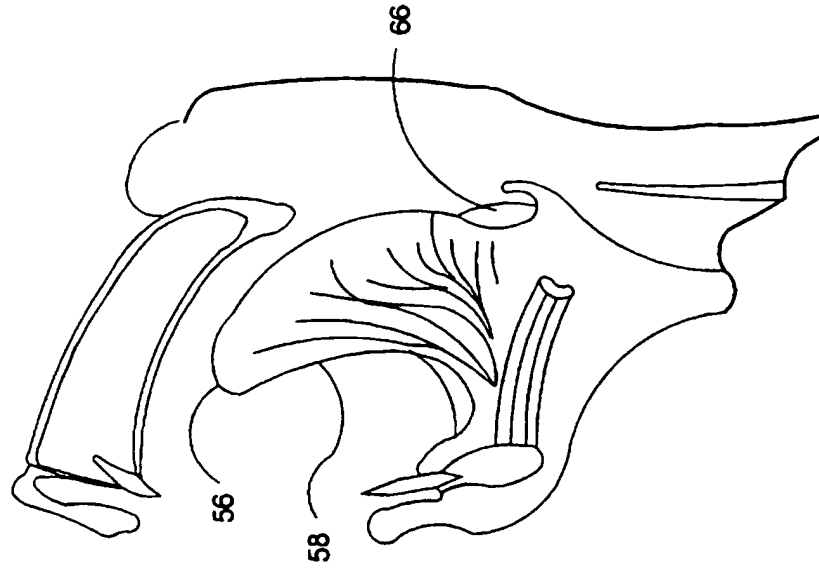


FIG. 15

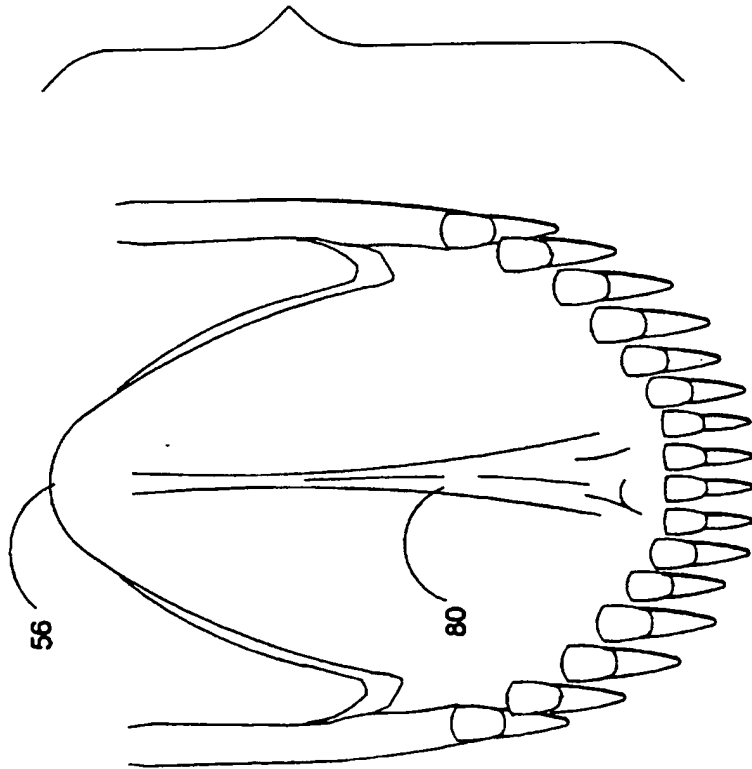


FIG. 14

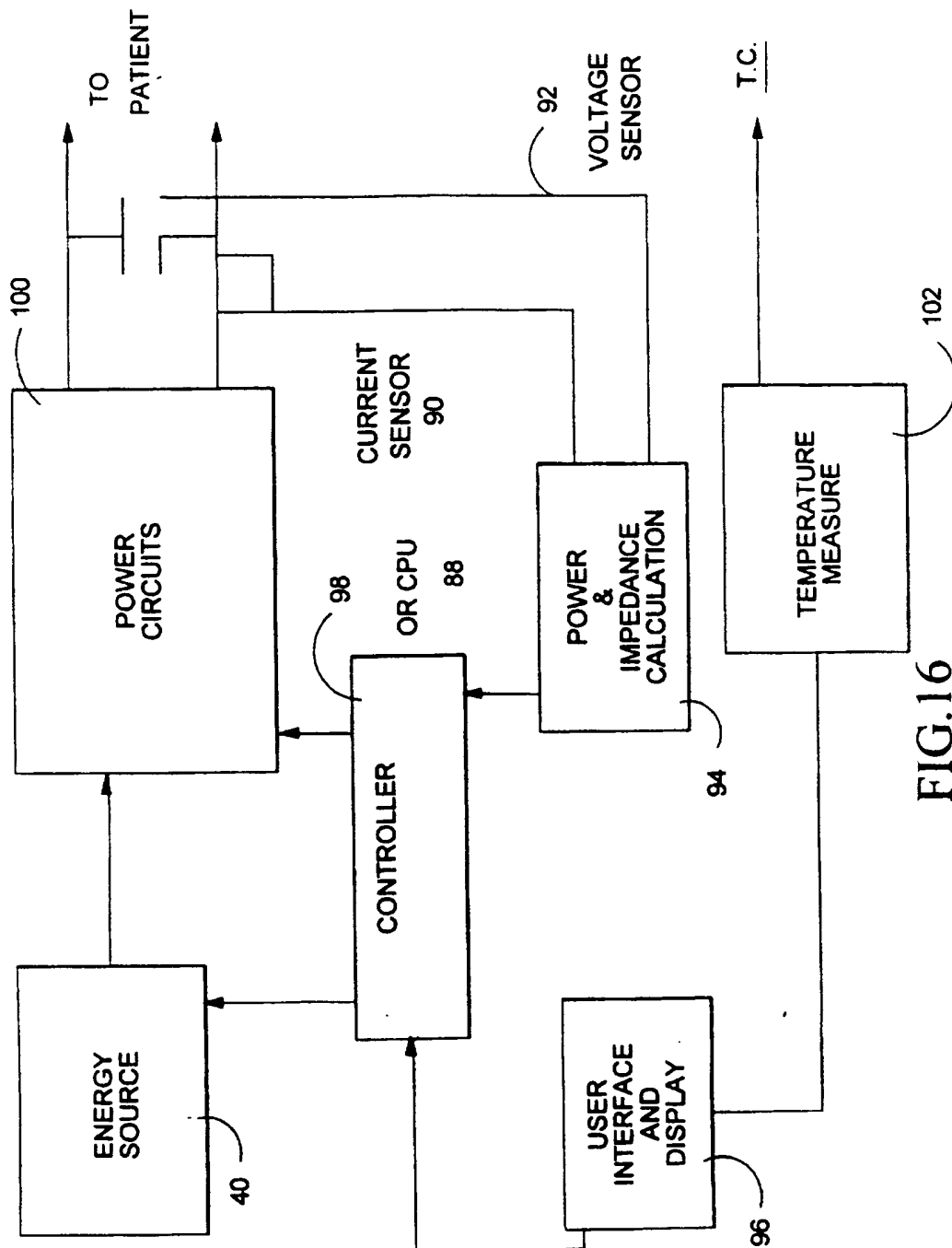


FIG. 16

12/17

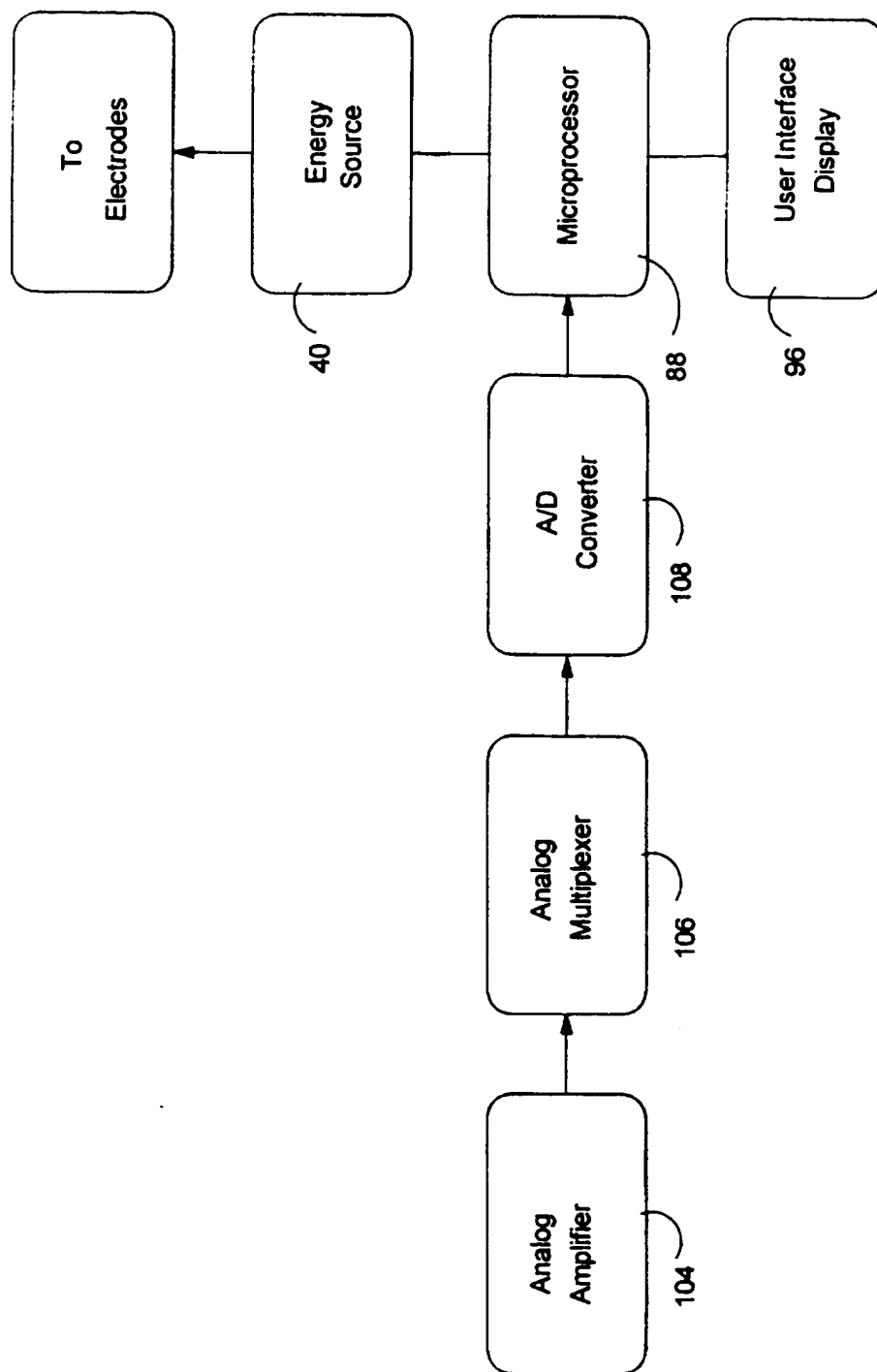


FIG.17

13/17

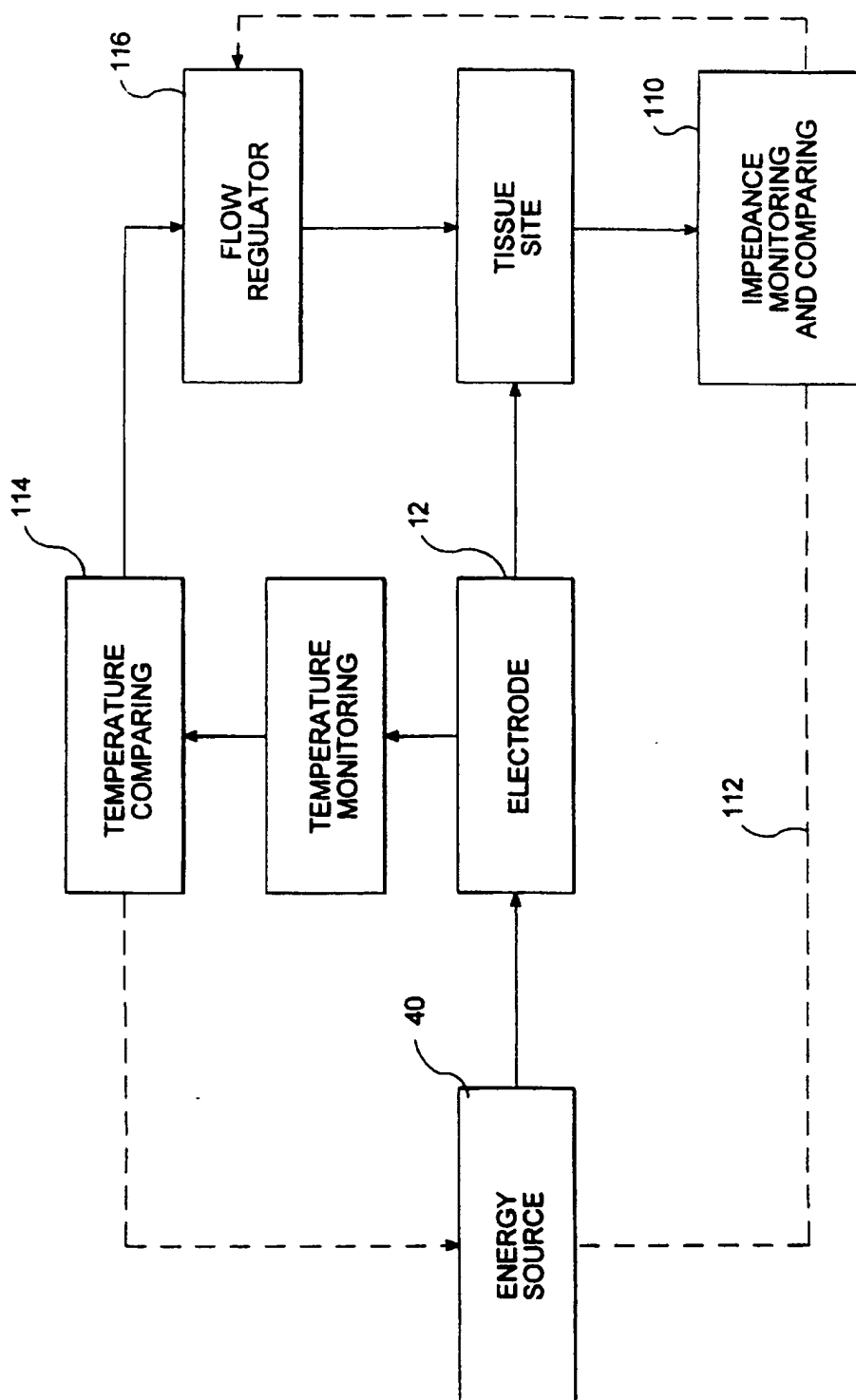


FIG. 18

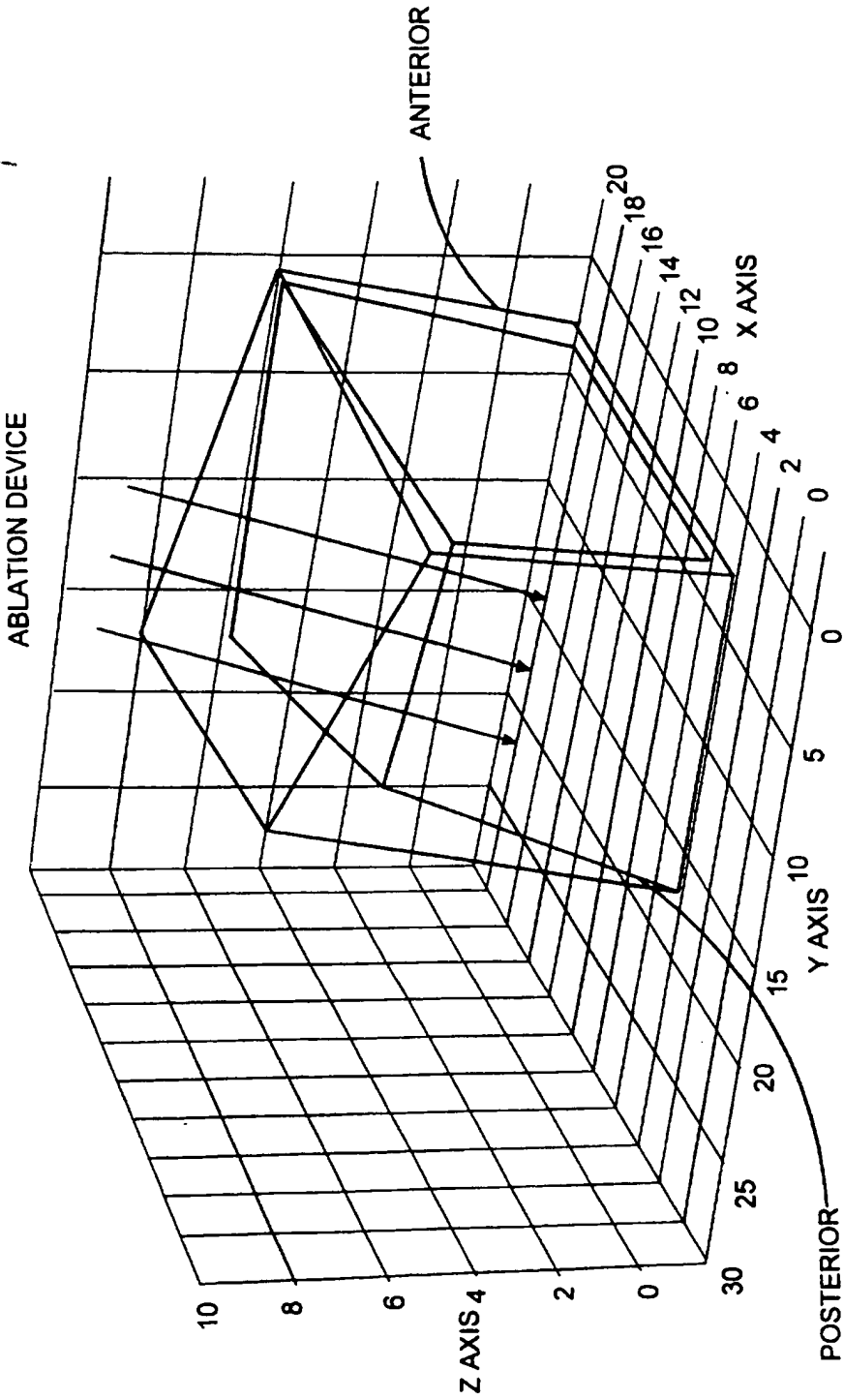


FIG. 19

AVERAGE SHRINKAGE IN Z DIRECTION = 20%

15/17

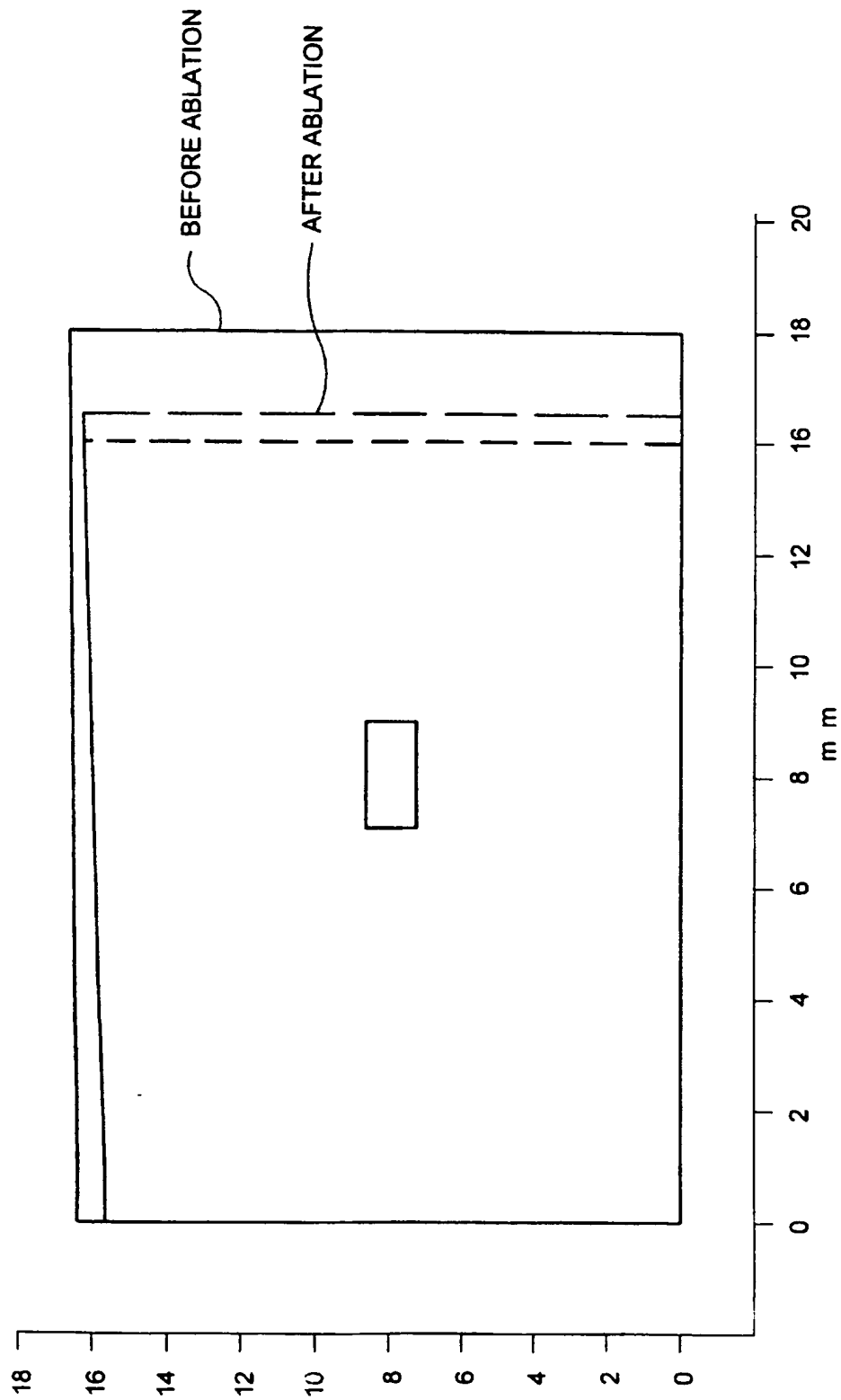


FIG. 20

16/17

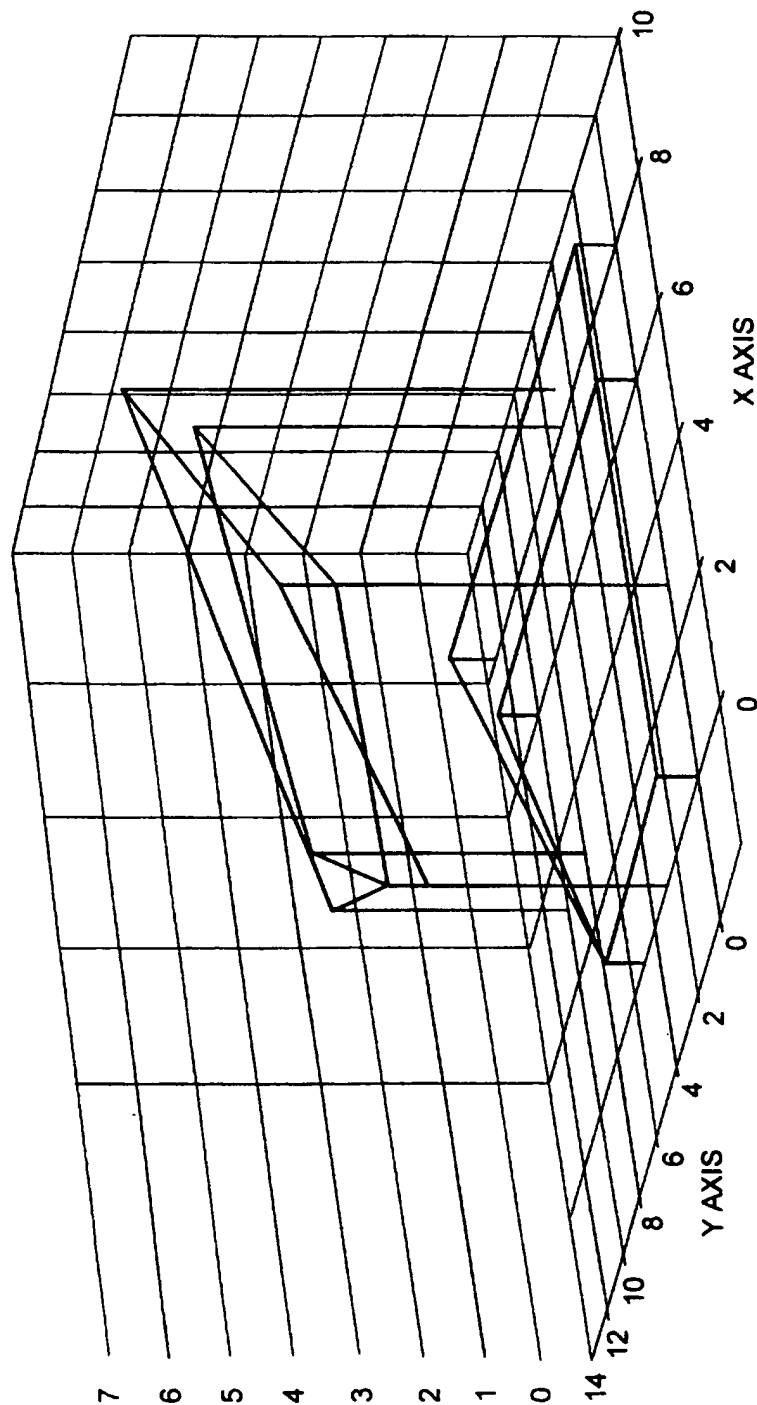


FIG. 21

17/17

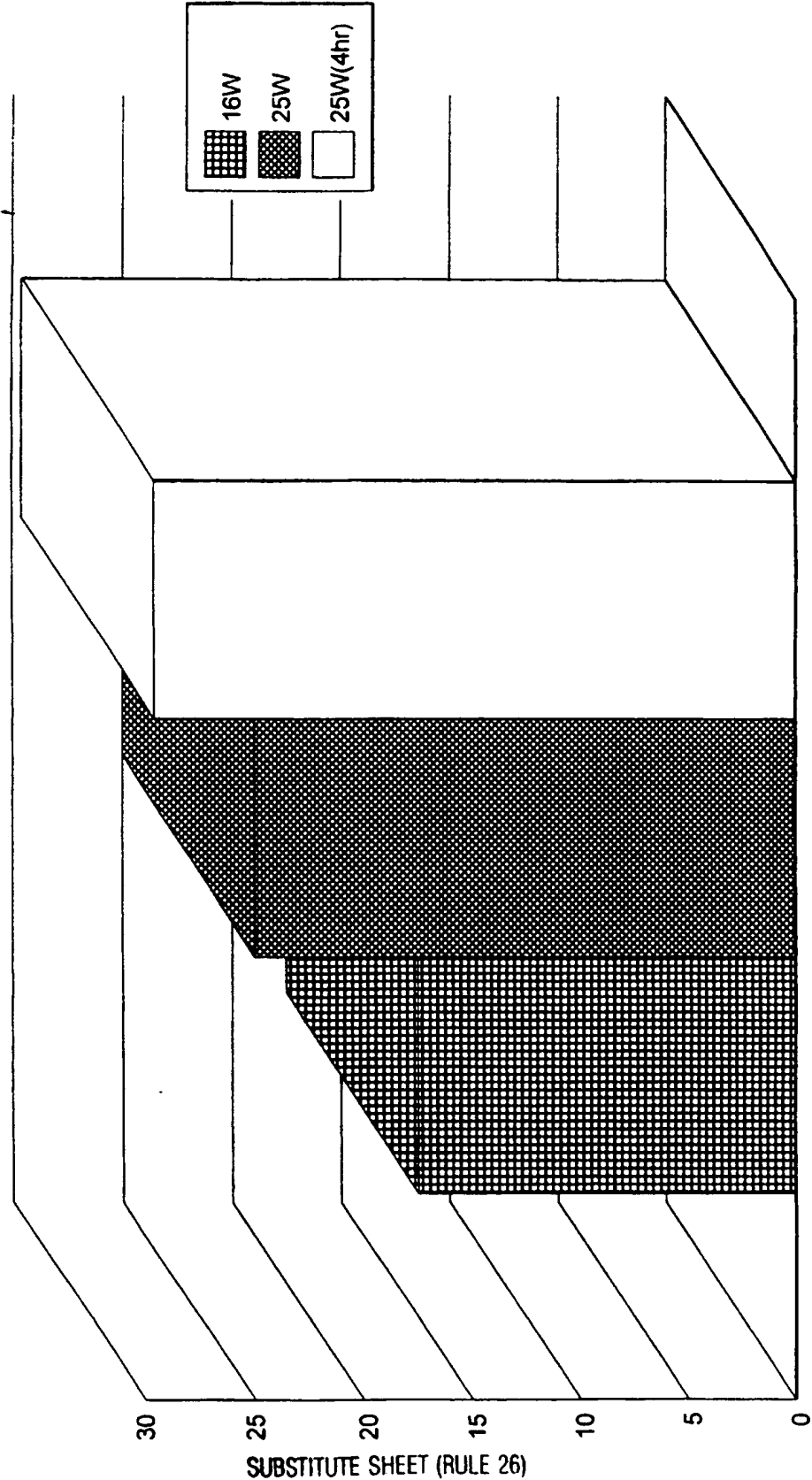


FIG. 22

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 97/08830

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61B17/39

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
	- / - -	

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

X document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

Y document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

& document member of the same patent family

Date of the actual completion of the international search

25 September 1997

Date of mailing of the international search report

20.10.97

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+ 31-70) 340-2040, Tx. 31 651 epo nl,
Fax (+ 31-70) 340-3016

Authorized officer

Papone, F

INTERNATIONAL SEARCH REPORT

Internat. J. Application No.
PCT/US 97/08830

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 95 25472 A (VIDAMED) 28 September 1995	1-3,6,8, 11, 13-16, 19,20, 23,24, 26-28, 31,32, 36, 38-40, 43,44, 47-50
Y	see the whole document	4,5,7,8, 10,12, 17,18, 21,25, 29,30, 33,35, 37,41, 42,45
Y	note ref. sign 42 ---	
Y	WO 94 10925 A (AMERICAN CARDIAC ABLATION) 26 May 1994 see abstract; figures FIG1,12 see page 9, line 32 - line 33 see page 9, paragraph 4 ---	4,5,7, 17,18, 29,30, 41,42
A	EP 0 608 609 A (CARDIAC PATHWAYS CORP.) 3 August 1994 see abstract; figure 1 ---	4,5,7, 12,17, 18,25, 29,30, 37,41,42
Y	DE 38 38 840 A (FISCHER) 23 May 1990 see column 9, line 51 - line 69; figure 9 ---	8,10,21, 33,35,45
Y	US 5 472 441 A (EDWARDS) 5 December 1995 see column 16, line 29 - line 60 -----	12,25,37

INTERNATIONAL SEARCH REPORT

Information on patent family members

Intern. al Application No

PCT/US 97/08830

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9525472 A	28-09-95	US 5484400 A US 5542916 A AU 2196595 A	16-01-96 06-08-96 09-10-95
WO 9410925 A	26-05-94	US 5342357 A AU 5544894 A EP 0746250 A US 5437662 A	30-08-94 08-06-94 11-12-96 01-08-95
EP 608609 A	03-08-94	US 5348554 A AU 673015 B AU 5201993 A CA 2110309 A JP 2562861 B JP 6254103 A US 5423811 A US 5545161 A US 5658278 A	20-09-94 24-10-96 16-06-94 02-06-94 11-12-96 13-09-94 13-06-95 13-08-96 19-08-97
DE 3838840 A	23-05-90	NONE	
US 5472441 A	05-12-95	US 5458597 A AU 1051495 A WO 9513113 A US 5536267 A US 5507743 A US 5599345 A US 5599346 A	17-10-95 29-05-95 18-05-95 16-07-96 16-04-96 04-02-97 04-02-97